The portion of the lower retainer 32 defining the cavity 34 is of substantially uniform diameter which is slightly greater than the diameter of the vial barrel 42. The interior of the upper vial retainer 30 includes an inwardly extending annual portion or stop 60 dimensioned to prevent the drug cartridge 40 from moving within the vial retainers 30, 32. In this way, when the drug cartridge 40 is inserted into the cavity 34 and the vial retainers 30, 32 threadedly engaged, the drug cartridge 40 is securely held in the cavity 34 at the open proximal end 44B of the tubular barrel 42 by the annual stop 60. More particularly, the neck 48 and crimped metallic sleeve 52 of the drug cartridge 40 are inserted in a proximal to distal direction into the open proximal end of the lower retainer 32 with the crimped metallic sleeve 52 eventually passing entirely into the lower retainer 32, which will require entry of the crimped metallic sleeve into the portion thereof for mounting the needle cannula assembly. Then, with the vial retainers 30, 32 threadedly engaged, the open proximal end 44 of the drug vial 40 abuts the stops 60 of the upper vial retainer 30.

Preferably, when using standard drug vials or cartridges 40, the vial retainers 30, 32 are permanently secured to one another by glue, locking threads or other fastening means. In this way, the cartridge assembly 14 with the drug vial 40 secured therein may disposed of after being used.

The pen body assembly 12 includes an array of threads 62 for threaded engagement with the threaded other end 36B of the upper vial retainer 30, and when threadedly engaged, the plunger 54 is disposed in sliding fluid tight engagement in the cartridge assembly 40. As shown in Fig. 3, the lead screw 22 initially is disposed substantially adjacent the plunger 54 of the drug cartridge 40. The portion of drug cartridge 40 between the plunger 54 and the seal 50 is filled with a medication 66. In this way, advancement of the plunger 54 causes the medication 66 to be forced from the drug cartridge 40 through the needle cannula.

Preferably, the pen body assembly 12 is reusable and the drug cartridge 40 in the cartridge assembly 14 will contain a volume of medication 66 sufficient for administration of several doses. After exhaustion of the medication 66, the cartridge assembly 14 will be threadedly disengaged from pen body assembly 12 and the drug cartridge 40 discarded. A new assembly containing a drug cartridge may then be mounted to the reusable pen body assembly 12.

The assembled reusable pen body assembly 12 and cartridge assembly 14 may be stored until a selected dose of medication is required. Just prior to use, a needle cannula assembly may be threadedly engaged to distal end 38B of cartridge assembly 14. This threaded engagement will cause a proximal tip of a needle cannula to the pierce the seal 50 and provide communication with medication 66.

A desired dose of medication may be set by rotating a dose knob 70 located at the distal end 20 of the pen which will cause advancement of the lead screw 22 into the cavity 34 of the cartridge assembly 14. When the desired dose is set, injection is achieved by merely pushing on actuator button 72 and the lead screw 22 will be advanced axially into cartridge assembly 14. This axial advancement of lead screw 22 causes distal end 24 thereof to come in contact with the plunger 54 and urge the plunger distally into the drug cartridge 40, and hence causes the medication 66 to be injected through the needle cannula. Injection will be terminated when the dose knob 70 is fully depressed into engagement with the pen body assembly 12.

Upon completion of the injection, the needle cannula assembly may be disengaged from the cartridge assembly 14 and safely discarded. The cap 16 may be mounted over cartridge assembly 14, and the pen 10 may be stored or carried in a

convenient location until the next dose of medication is required. A subsequent dose of medication will be set in exactly the manner as described above. However, for such a subsequent dose, the plunger 54 will be in a partly advanced position as a starting point. Dose setting and injections can be carried out until all of medication 66 has been used. The cartridge assembly 14 may then be threadedly disengaged from pen body assembly 12, and slidably separated from the lead screw 22 and discarded in order to be replaced as described above.

Fig. 6 shows an alternative embodiment of the cartridge assembly 114 which is disposable and includes an upper vial retainer 130 and a lower vial retainer 132. In this embodiment, once a drug cartridge 140 is placed in the cavity 134, the vial retainers 130, 132 are permanently secured to one another by glue or other fastening means 190. In this way, upon utilization of the medication, the drug cartridge assembly 114 along with the empty drug cartridge 140 may be disengaged from the pen body assembly and safely discarded.

Fig. 7 shows another alternative embodiment of the cartridge assembly 214 which is disposable and is in the form of a single integral unit having a generally tubular barrel 242 with a distal end 244A defined by an inwardly converging shoulder 246 and an open proximal end 244B. A smaller diameter neck 248 projects distally from the shoulder 246 of the barrel 242, and is provided with a pierceable and resealable elastomeric seal or septum 250 securely mounted across the open distal end defined by the neck 248. Medication is pre-filled into the integral cartridge assembly 214 and is retained therein by an elastomeric stopper or plunger 254. The plunger 254 is in sliding fluid-tight engagement with the tubular wall of the barrel 242. Distally directed forces on the plunger 254 urge the medication from the pen as explained interconnection with the preferred embodiment. In this embodiment, the proximal

end 244B of the integral cartridge assembly 214 include bayonet threads 280 which are engageable with corresponding grove 282 formed in the distal end of the pen body 212. The distal end 244A of the tubular barrel is configured to securely but releasably engage a needle cannula assembly (not shown).

The cartridge assembly 214 shown in Fig. 7 may be assembled and pre-filled by any suitable means, including those disclosed, for example, in U.S. Patent Nos. 5,279,585 (Balkwill), 5,531,255 (Vacca), 5,519,984 (Veussink et al.), 5,373,684 (Vacca), 5,207,983 (Liebert et al.), 4,718,463 (Jurgens, Jr. et al.), and 4,628,969 (Jurgens, Jr. et al.), and PCT Application No. WO 94/13328 (Hagen), the disclosures of which are hereby incorporated by reference in their entirety.

Fig. 8 shows yet another alternative embodiment of the cartridge assembly 314 which is disposable end includes single vial retainer 332. However, a stop has been situated in the distal end 338B of the vial retainer 332 which permit the drug cartridge 340 to be inserted into the cavity 334 in one direction but resists removal of the drug cartridge, i.e., the insertion force is less than the removal force. Specifically, protrusions 360 project inwardly and extend along the neck 348 of the drug cartridge 40 to securely retain it in the cartridge assembly. In this way, upon utilization of the medication, the drug cartridge assembly 314 along with the empty drug cartridge 340 may be disengaged from the pen body assembly and safely discarded.

Fig. 9 shows yet another alternative embodiment of the cartridge assembly 414 which is disposable and includes single vial retainer in which a flexible vial or drug container 440 such as a pouch can be inserted into the cartridge assembly. Attached by treads or the like to the end 438B of the cartridge assembly is a cannula 490 having a double ended needle 492. In this way, upon movement of the plunger or stopper

454, the proximal end of the needle 492 pierces the drug container to permit the drug to be released therefrom as the container collapses.

The particular material of which the cartridge assembly is made is not essential to the present invention but preferably includes a polymeric material such as polycarbonate. However, the particular material is a matter of choice depending upon availability, the manufacturing process used and the intended use of the cartridge assembly. For example, where the cartridge assembly 214 is pre-filled with the medication, the polymeric material must be compatible with the medication contained therein.

It should be appreciated from the detailed description of the preferred embodiments, that the particular means by which the pen body assembly 12 and the cartridge assembly are keyed, i.e., engaged so as to reduce or otherwise eliminate cross-use is essential and may be threadedly engaged by corresponding threads and grooves, bayonet threads and grooves, snap fits or a pair of lugs that mate in a reverse Luer-lock manner. In this way, the pen body assembly 12 includes either a female or male mating member and the cartridge assembly 14 includes a corresponding female or male mating member engageable with one another for interconnecting the two assemblies, with the mating members selected so as to prevent cross-use with other assemblies, e.g., the pitch of the threads may be angled so as to mate only with one another and not with other assemblies.

Also, the cartridge holder sleeve can have an embedded cartridge, not readily separable from each other as described in connection with one alternative embodiment. In addition, the drug cartridge can be designed as a single integral unit

for containing the drug as described in connection with another alternative embodiment.

While the preferred embodiments of the present invention have been described so as to enable one skilled in the art to practice the device of the present invention, it is to be understood that variations and modifications may be employed without departing from the concept and intent of the present invention as defined in the following claims. The preceding description is intended to be exemplary and should not be used to limit the scope of the invention. The scope of the invention should be determined only by reference to the following claims.

What is claimed is:

1. A disposable, pre-fillable drug cartridge for use with a reusable body assembly of a medication delivery pen, said drug cartridge comprising:

a generally tubular barrel having a distal end and an open proximal end, with a chamber defined by a tubular wall of the barrel extending between said distal end and said proximal end;

sealing means associated with the distal end of said tubular barrel for sealing the distal end of said tubular barrel;

plunger means associated with the open proximal end of said tubular barrel in sliding fluid-tight engagement with the tubular wall of the barrel for selective engagement with an advancing member so that distally directed forces on the plunger urge a medication pre-filled in the chamber from the cartridge; and

mating means for releasably interconnecting said drug cartridge with a pen body assembly and said mating means being associated with the proximal end of said tubular barrel.

2. The drug cartridge of Claim 1, wherein said mating means includes an array of threads on said proximal end of said tubular barrel.

3. The drug cartridge of Claim 2 wherein said array of threads on the proximal end of said tubular barrel define internal threads in said tubular barrel.

4. The drug cartridge of Claim 1 wherein said distal end of the tubular barrel is configured to securely but releasably engage a needle cannula assembly.

5. The drug cartridge of Claim 1 wherein said generally tubular barrel is made of a polymeric material.

6. The drug cartridge of Claim 1 further comprising a medication contained in said chamber.

7. A disposable, pre-fillable drug cartridge for use with a reusable body assembly of a medication delivery pen, said drug cartridge comprising:

a generally tubular barrel made of a polymeric material having a distal end and an open proximal end, with a chamber defined by a tubular wall of the barrel extending between said distal end and said proximal end;

sealing means associated with the distal end of said tubular barrel for sealing the distal end of said tubular barrel;

an elastomeric plunger associated with the open proximal end of said barrel in sliding fluid-tight engagement with the tubular wall of the barrel;

medication contained in the chamber and retained therein by the seal and plunger so that distally directed forces on the plunger urge the medication from the cartridge; and

mating means for releasably interconnecting said drug cartridge with a pen body assembly and said mating means being associated with the proximal end of said tubular barrel.

8. The drug cartridge of Claim 7, wherein said mating means includes an array of threads on said proximal end of said tubular barrel.

9. The drug cartridge of Claim 8 wherein said array of threads on the proximal end of said tubular barrel define internal threads in said tubular barrel.

10. The drug cartridge of Claim 7 wherein said distal end of the tubular barrel is configured to securely but releasably engage a needle cannula assembly.

11. The drug cartridge of Claim 7 wherein said medication is contained within a flexible container and a needle cannula attached to distal end of the tubular barrel with said cannula included a double ended needle so that one end of said double ended needle can pierce said flexible container.

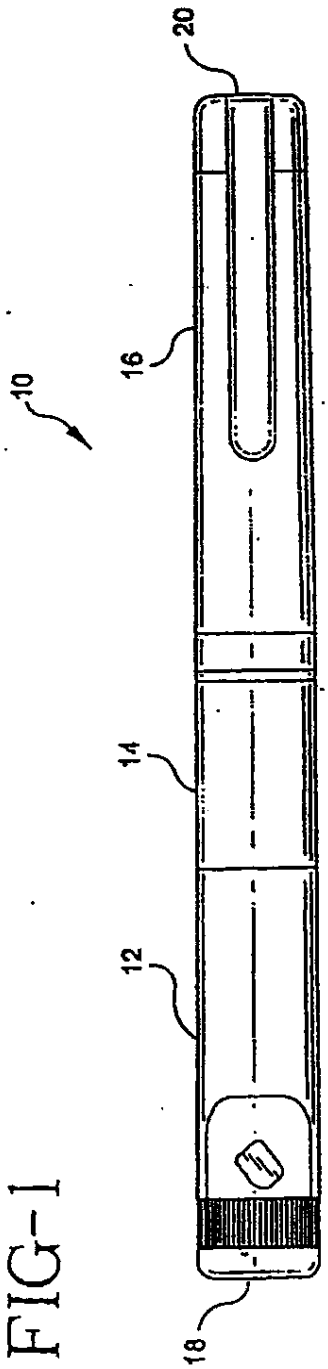

FIG-1

FIG-1A

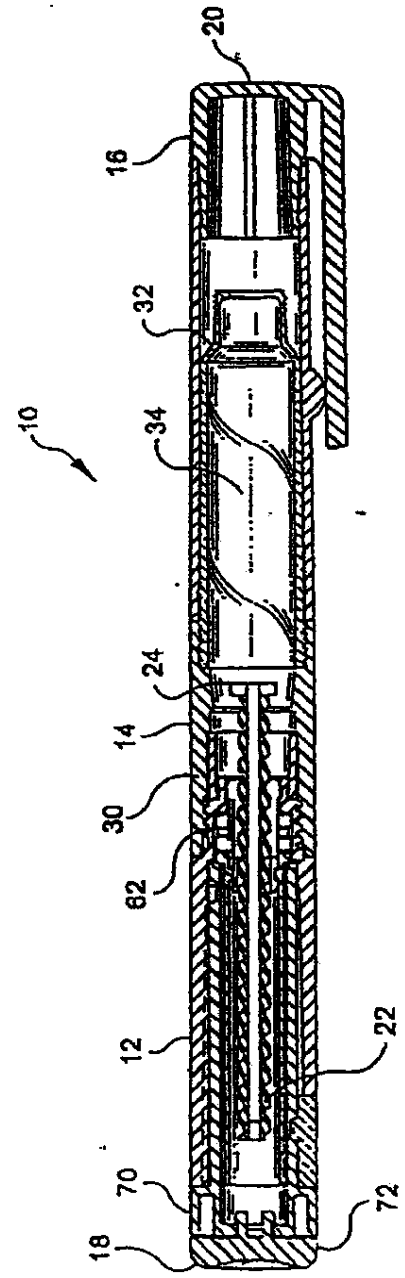

FIG-2

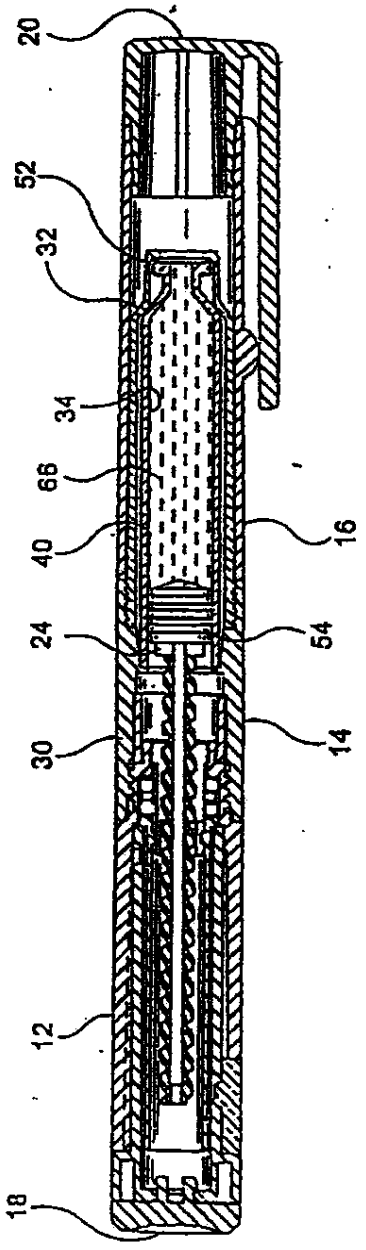

FIG-3

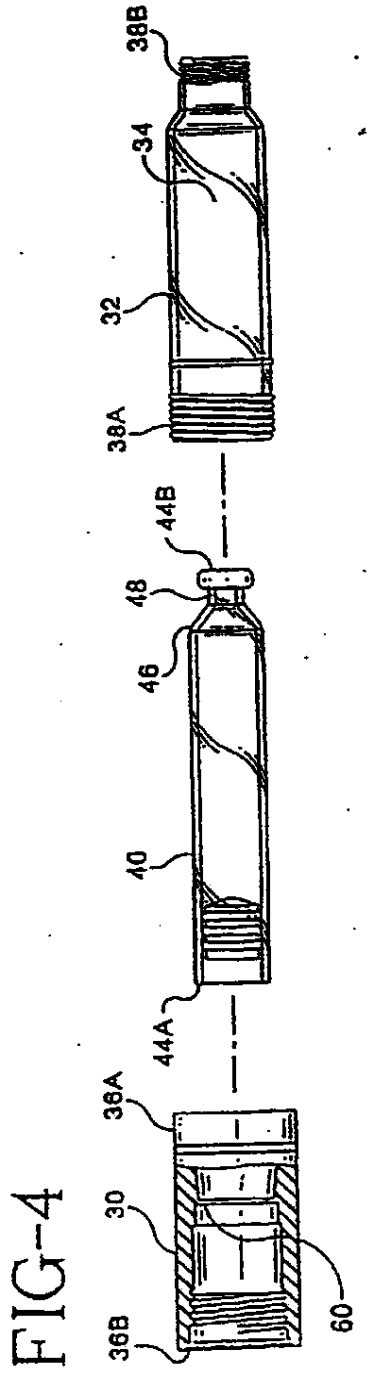

FIG-4

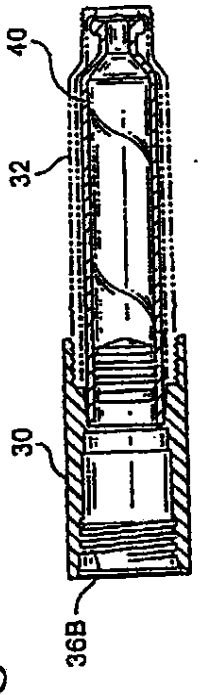

FIG-5

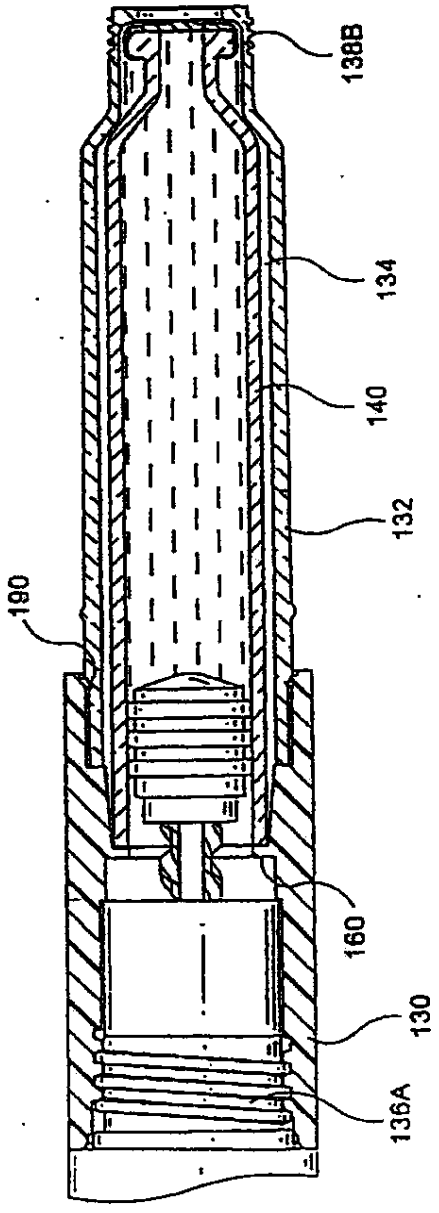

FIG-6

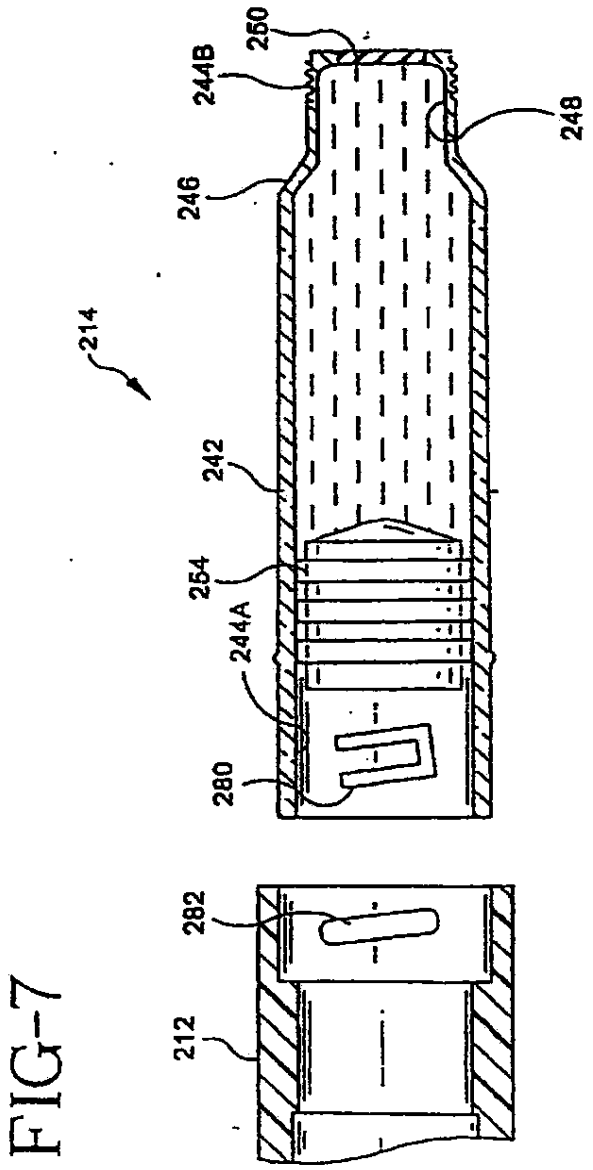

FIG-7

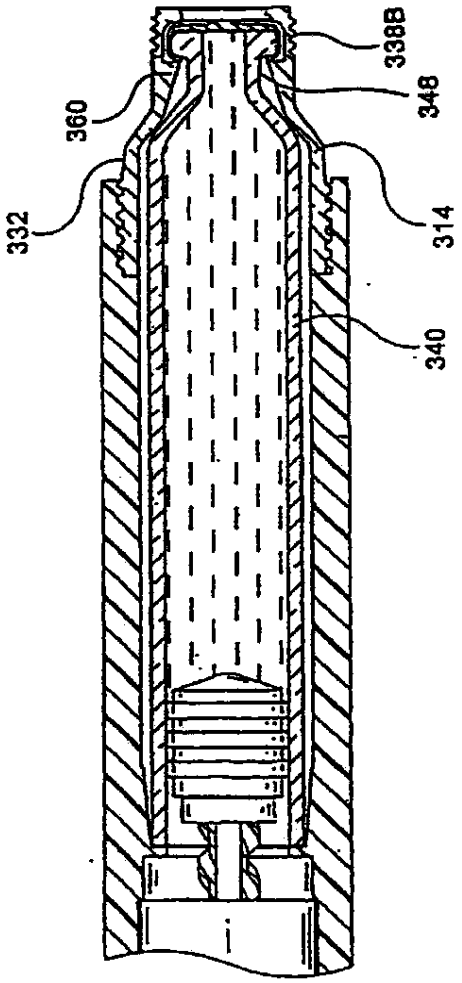

FIG-8

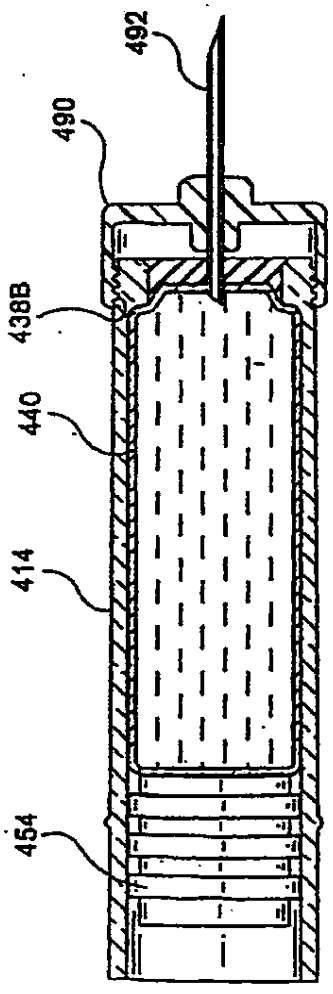

FIG-9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/19649

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 91 17 140 U (HOECHST AG) 20 June 1996 see page 2, line 19 - line 23 see page 2, line 28 - line 30 see figures 1,4	1,6
Y	---	2-5,7
Y	WO 90 00073 A (BRUNEL) 11 January 1990 see page 4, line 5 - line 6 see page 7, line 11 - line 1 see claim 1; figures 3,6,9	5,7
A	---	1
Y	US 2 685 878 A (SEIFERT ET AL.) 10 August 1954 see column 2, line 11 - line 16 see figures 1,2	2-4
A	---	8-10
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[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 January 1999	19/01/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Sedy, R

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/19649

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR 1 320 820 A (STEINER) 4 June 1963 see page 2, right-hand column, line 53 - page 3, left-hand column, line 13 see figure 5	11
A	EP 0 701 832 A (BECTON DICKINSON AND COMPANY) 20 March 1996 see column 6, line 21 - line 25 see column 8, line 32 - line 48 see figure 1 see claims 1,10; figure 1 & US 5 558 259 A cited in the application	1,4-7,10

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

information on patent family members

International Application No
PCT/US 95/19649

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
DE 9117140	U	20-06-1996	DE	4025717	A	20-02-1992
			CA	2049092	A	15-02-1992
			EP	0471335	A	19-02-1992
			IE	68055	B	15-05-1996
			IT	229112	Y	24-06-1998
			JP	4244166	A	01-09-1992
			PT	98656	A	30-09-1993
			US	5728076	A	17-03-1998
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			EP	0393166	A	24-10-1990
US 2685878	A	10-08-1954	NONE			
FR 1320820	A	04-06-1963	NONE			
EP 701832	A	20-03-1996	US	5549575	A	27-08-1996
			CA	2156696	A	14-03-1996
			JP	8098886	A	16-04-1996

Form PCT/ISA/210 (patent family annex) (July 1992)

Pens: Partfill ?

TBa → HEHa 96 08 28

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Office européen des brevets

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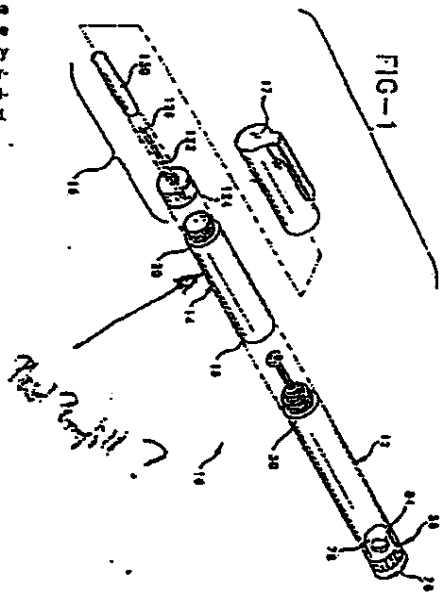
(54) Medication delivery pen with variable increment dose scale

(57) A medication delivery pen is provided having a pen body assembly and a cartridge assembly that are threadedly engageable with one another. The pen body assembly includes a rotatable driver for driving a cartridge plunger preselected distances that are in accordance with a desired dose of medication to be delivered. The driver providing different preset rates of injection.



FIG—1

Real Refill ?

EP 0 702 970 A2

Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

The subject invention relates to medication delivery pens having a cartridge holder assembly and a pen body assembly removably mounted to the cartridge holder assembly for delivering medication having an improved dose setting device.

2. Description of Related Art

Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula is mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the prior art vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication is drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula is withdrawn from the vial, and the medication is injected into a patient by moving the plunger in a distal direction.

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a vial holder into which a vial of insulin or other medication may be received. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the prior art vial holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This prior art medication delivery pen is used by inserting the vial of medication into the vial holder. A prior art pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose.

The user of the pen mounts a prior art double-ended needle cannula to the distal end of the vial holder such that the proximal point of the needle cannula pierces the elastomeric seal on the vial. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The patient then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used as explained above.

The above described medication delivery pen is effective and much more convenient for self-administration of medication than the typical hypodermic syringe and separate medication vial. However, prior art medication delivery pens are limited to a particular range of dosage amounts because of the fairly complex dosage selecting and driving mechanisms within the delivery pens. To vary the dosage amounts available to a user would require more complex devices that are costly to manufacture. Hence, it is necessary to provide a medication delivery pen at a reasonable cost having a wider range of doses and more flexibility when setting doses for drug delivery.

SUMMARY OF THE INVENTION

The subject invention relates to a medication delivery pen having a medication cartridge assembly that is selectively engageable with and disengageable from a

pen body assembly. The medication cartridge assembly is an elongate generally cylindrical structure having opposed proximal and distal ends. The distal end of the medication cartridge assembly includes needle mounting means for securely but releasably receiving a needle cannula assembly, the distal end being characterized by a pierceable elastomeric seal that may be repeatedly and resealably pierced by the proximal end of a double-ended needle cannula. The proximal end of the medication cartridge assembly includes body mounting means for securely but releasably mounting the medication cartridge assembly to the pen body assembly. The body mounting means may comprise an array of threads extending distally from the proximal end of the medication cartridge assembly.

The medication cartridge assembly further includes plunger means slidably disposed in fluid tight engagement therein. The plunger means may initially be disposed in a proximal position within the medication cartridge assembly and may be moved in a distal direction by a driver projecting from the pen body assembly. The medication cartridge assembly further comprises anti-rotation means for preventing rotation of the driver.

The pen body assembly of the subject invention comprises an array of mounting threads to enable threaded engagement of the pen body assembly and the medication cartridge assembly and an actuator button rotatably mounted on its proximal end. Thus, axial forces exerted on the actuator button cause the pen body assembly to threadedly engage the medication cartridge assembly.

The pen body assembly further includes a lead screw for selectively engaging the plunger of the cartridge assembly and for urging the plunger of the cartridge assembly in a distal direction. At least a portion of the lead screw includes driving threads engaged with other portions of the pen body assembly that may be operative to achieve axial movement of the lead screw in response to axial forces exerted on the rotatable actuator button. The pen body assembly further comprises dose setting means for establishing and precisely controlling the amount of medication to be delivered in response to each actuation of the actuator button. The dose setting means may be any of several structures as described in greater detail below.

A cartridge assembly that is filled with medication is mounted to the pen body assembly and the initial response to forces on the actuator button cause the lead screw to move in a proximal direction toward its starting position, while the remaining portions of the pen body assembly move distally toward the vial assembly. Further forces exerted on the actuator button cause the mounting means of the pen body to engage the mounting means of the cartridge assembly. Continued axial forces on the actuator button cause the mounting threads to engage the cartridge assembly and continue the proximal movement of the driver. The pen body assembly is fully but releasably engaged with the cartridge assembly at the same time that the driver is at its proximal extreme position and is then in position to begin delivering selected doses of medication from the pen. Doses of medication can be dispensed as needed over time, and the cartridge assembly is removed and discarded when the medication therein has been exhausted. A new medication cartridge assembly may then be mounted to the pen body assembly as described above.

The driving means in the pen body assembly of the present invention includes a dose setting knob having a helical groove with three different regions of operation, each region having a different pitch to provide three different types of dosage increments. For example, the dose setting increments in the first region are 0.5 within a dose range of 0 to 10 units, 1.0 in the 10 to 30 unit range of the second region, and 2.0 for doses above 30 units in the third region. This approach to dose setting and the associated resolution (ability to select a particular dose) is believed to be more consistent with the way insulin doses are prescribed by physicians and the way patients are instructed to adjust their own insulin dose.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of the medication delivery pen of the subject invention.

Fig. 2 is an exploded perspective view of the pen body assembly of the medication delivery pen shown in Fig. 1.

Fig. 3 is a side view of the periphery of a dose knob of the present invention operating in a first region and projected on a plane.

Fig. 4 is a side view of the periphery of a dose knob of the present invention operating in a second region and projected on a plane.

Fig. 5 is a side view of the periphery of a dose knob of the present invention operating in a third region and projected on a plane.

DETAILED DESCRIPTION

A medication delivery pen in accordance with the subject invention is identified generally by the numeral 10 in Fig. 1. Medication delivery pen 10 includes a pen body assembly 12, a cartridge assembly 14, a needle cannula assembly 16 and a cap 17. Cartridge assembly 14 includes opposed proximal and distal ends 18 and 20, respectively. Proximal end 18 of cartridge assembly 14 is dimensioned and configured to threadedly engage pen body assembly 12, as explained further herein. Distal end 20 of cartridge assembly 14 is configured to securely but releasably engage needle cannula assembly 16 and a shield 130 is provided to cover a distal end 126 of a needle cannula 122 in needle cannula assembly 16.

The preferred embodiment of pen body assembly 12 is illustrated in greater detail in Fig. 2. It is understood, however, that variations from this preferred embodiment is provided, and are considered to be within the scope

of the subject invention. Pen body assembly 12 includes a generally cylindrical housing 22 having opposed proximal and distal ends 24 and 26, and a substantially hollow throughbore 28 extending axially therethrough. An array of external threads 30 extends proximally from distal end 26 for threaded engagement with proximal end 16 of cartridge holder assembly 14. Portions of hollow throughbore 28 of housing 22 adjacent distal end 26 are characterized by an array of clutch teeth (not shown) molded therein. Proximal end 24 of housing 22 is characterized by a cut-out 33 formed therein for receiving a window insert 78.

Pen body assembly 12 includes a nut 34 having opposed proximal and distal ends 36 and 38, respectively. Exterior surface regions of nut 34 between proximal and distal ends 36 and 38 define a plurality of longitudinally extending splines 39. Proximal end 36 of nut 34 also includes a plurality of longitudinally extending resilient fingers 40 with enlarged ends that enable snap engagement of nut 34 into other portions of pen body assembly 12, as explained further herein. Distal end 38 of nut 34 is radially enlarged to limit axial movement of nut 34 in distal end 26 of housing 22. Thus, nut 34 is axially constrained within housing 22, however, the dimensions and configurations of nut 34 and housing 22 permit free relative rotation therebetween.

Pen body assembly 12 includes a clutch assembly 42 mounted therein. Clutch assembly 42 includes a proximal clutch 44, a distal clutch 46 and an annular spring 48 biasingly engaged therebetween. Proximal and distal clutches 44 and 46 each are configured for non-rotatable engagement over splines 39 of nut 34. Distal clutch 46 includes an array of distally facing saw teeth, dimensioned, disposed and configured for engagement with clutch teeth (not shown) on the interior distal end of housing 22, such that distal clutch 46 can rotate only in one direction relative to housing 22. Proximal clutch 44 includes an array of proximally facing teeth which are also configured for unidirectional rotation, as explained further herein.

Pen body assembly 12 includes a generally cylindrical driver 50 having opposed proximal and distal ends 52 and 54. Driver 50 is slidably inserted into housing 22 of pen body assembly 12 such that distal end 54 of driver 50 is snap fit over the enlarged ends of resilient fingers 40 at proximal end 36 of nut 34. This snap fit engagement prevents axial movement between nut 34 and driver 50, but permits free relative rotational movement within housing 22. Distal end 54 of driver 50 is also characterized by an array of saw teeth 49 that engage with the saw teeth on proximal clutch 44. Outer surface regions of driver 50 are characterized by splines 56 extending radially outwardly thereon and along a substantial portion of the length of driver 50.

Pen body assembly 12 includes a dose knob 58 which is a hollow generally cylindrical structure having opposed proximal and distal ends 60 and 62 and opposed inner and outer surfaces 64 and 66. Inner surface 64 is characterized by longitudinally extending grooves 68 which are disposed and dimensioned for engagement with splines 56 on driver 50. More particularly, dose knob 58 is spline mounted over driver 50 within housing 22 of pen body assembly 12. Thus, axially extending grooves 68 in dose knob 58 engage splines 56 of driver 50 to prevent relative rotation therebetween, but permitting relative axial movement.

Figs. 3-5 are side views of the periphery of dose setting knob 58 projected on a plane and show button 66 operating in a first, second and third region, respectively. As shown in Figs. 3-5, outer surface 66 of dose knob 58 is characterized by a groove 70 comprised of three regions, each region having a helical component 174, 184, 194. Each helical component has a different pitch to provide different dose increments in each region of dose setting knob 58 and thereby improve resolution and provide a greater range of potential dosage settings for the pen. Outer surface 66 adjacent each helical component 174, 184, 194 of groove 70 is provided with dosage indicia to define dose setting increments corresponding to each region of groove 70. For example, the dose setting increments are 0.5 in the dose range 0 to 10 units of helical component 174, 1.0 in the 10 to 30 unit range of helical component 184, and 2.0 for doses above 30 units in helical component 194. The present invention provides dosage resolution very consistent with the way insulin doses are prescribed by physicians, and the way patients are instructed to adjust their own insulin dosages.

Proximal end 60 of dose knob 58 is characterized by a grained exterior surface to facilitate manipulation for setting a selected dose. An actuator button 76 is snapped into engagement with proximal end 60 of dose knob 58 to permit relative rotation therebetween. An insert 78 is snapped into engagement with cut-out 33 in proximal end 24 of housing 22. Insert 76 including opposed inner and outer surfaces 82 and 80 and a window 84 extending therebetween. Inner surface 82 of insert 78 includes a button 86, shown in Figs. 3-5, on inner surface 82 dimensioned and disposed to engage in groove 70 of dose knob 58. Button 66 and window 84 are also disposed to enable the indicia on dose knob 58 to be visible through window 84.

Pen body assembly 12 further includes a lead screw 88 with opposed proximal and distal ends 90 and 92 and an array of external threads 94. External threads 94 are characterized, however, by a pair of opposed axially extending grooves 96 which extend from distal end 92 substantially to the proximal end 90. Threads 94 are engaged in nut 34, such that proximal end 90 of lead screw 88 is within housing 22 and distal end 92 projects distally beyond housing 22. Threads 94 on lead screw 88 have exactly the same pitch and the same hand as threads 30 on distal end 26 of housing 22.

Pen body assembly 12 is assembled by placing nut 34 into housing 22 from distal end 26. Clutch assembly 42 then is mounted over splines 39 on nut 34. Driver 50 is then inserted into proximal end 24 of housing 22, and

is urged sufficiently in a distal direction for snap fit engagement with nut 34. In this snapped engagement, the saw teeth of distal clutch 46 will be secured in engagement with the teeth in housing 22, and the saw teeth of proximal clutch 44 will be engaged with saw teeth 49 at distal end 54 of driver 50. Spring 48 will maintain constant selected pressure between these interengaged saw teeth. Insert 78 then is positioned over dose knob 58 such that button 86 of insert 78 is engaged in groove 70 in dose knob 58. The temporarily assembled insert 78 and dose knob 58 then are urged into housing 22. Lead screw 88 then is threaded into nut 34, and actuator button 76 is snapped into engagement with proximal end 60 of dose knob 58.

The assembled pen body assembly 12 and cartridge assembly 14, shown in Fig. 1, is stored until a selected dose of medication is required. Just prior to use, needle cannula assembly 16 is threadedly engaged to distal end 20 of cartridge assembly 14. This threaded engagement will cause a proximal tip 124 of needle cannula 122 to pierce a seal on the medication cartridge and provide communication with medication therein. Shield 130 may then be removed. A desired dose of medication is set by rotating dose knob 58 until indicia corresponding to the desired dose appears in window 84 of insert 78. The engagement of button 86 on insert 78 in helical portions 174, 184, 194 of groove 70 in dose knob 58 causes a threaded retraction of dose knob 58 relative to housing 22 of pen body assembly 12. This threaded retraction of dose knob 58 will cause a simultaneous rotation of driver 50 splined thereto. However, nut 34 will not rotate because the saw teeth on distal clutch 46 and the saw teeth on interior portions of housing 22 are locked to prevent rotation in that direction. Proximal clutch 44 is splined to nut 34, and hence also will not turn. However, saw teeth 49 at distal end 54 of driver 50 are shaped to allow rotation relative to proximal clutch 44, and provide an audible click for each unit of medication in the selected dose. This is helpful for visually impaired patients who may be required to set doses and administer insulin or other medication to themselves. Annular spring 48 contributes to the engagement that provides these audible clicking sounds.

When the desired dose is set, injection is achieved by merely pushing on actuator button 76. This causes dose knob 58 to turn about helixes 174, 184, 194 relative to pen body housing 22, so that driver 50 rotates through the same number of degrees. As dose knob 58 turns about helixes 174, 184, 194, button 86 travels through helix 174 in the first region when dispensing 1 to 10 units of medication, helix 184 in the second region when dispensing 11 to 30 units of medication, and helix 194 in the third region when dispensing 31 to 50 units of medication. Dose setting knob 58 of the present invention therefore provides a wider range of dosages for the user than previously known dose setting knobs because of the different pitch of each helix, as shown in Figs. 3-5. Rotation of dose setting knob 58 is opposite to the rotation generated during the dose setting procedure, when the rotational freedom of clutch assembly 42 is reversed. As dose setting knob 58 turns during injection the previously clicking proximal clutch 44 is locked to and turns with driver 50. This driving movement of proximal clutch 44 causes a corresponding rotational movement of nut 34 because of the splined engagement therebetween. Distal clutch 46 is therefore free to rotate against the saw teeth in housing 22, and makes an audible clicking indication during injection of medication.

Rotation of lead screw 88 is prevented by grooves 96 and tabs unitarily molded within housing 100 of cartridge holder assembly 14. Therefore, as nut 34 rotates under the driving action of proximal clutch 44 and driver 50, lead screw 88 will be advanced axially into cartridge holder assembly 14. This axial advancement of lead screw 88 causes distal end 92 thereof to urge plunger 116 distally into cartridge 108, and hence causes a particular amount of medication to be injected through needle cannula 122 depending upon the dosage set using dose setting knob 58. Injection is terminated when proximal end 68 of dose knob 58 engages against proximal end 24 of pen body housing 22.

Upon completion of the injection, needle cannula assembly 16 may be disengaged from cartridge holder assembly 14 and safely discarded. Cap 17 may be mounted over cartridge holder assembly 14, and pen 10 may be stored or carried in a convenient location until the next dose of medication is required. A subsequent dose of medication will be set in exactly the manner as described above. However, for such a subsequent dose, lead screw 88 will be in a partly advanced position as a starting point. Dose setting and injections can be carried out until all of the medication has been used. Cartridge holder assembly 14 may then be threadedly disengaged from pen body assembly 12, and slidably separated from lead screw 88. The separated cartridge holder assembly may then be discarded and replaced as described above.

While the invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims. In particular, the pen body assembly may have other driving and/or clutch mechanisms. Additionally, different means for preventing and/or enabling rotation during the dose setting and injection phases may be provided. Similarly, other means for mounting needle cannula to the cartridge assembly may be provided. These various optional constructions will be apparent to those skilled in the art after having read the subject disclosure.

Claims

1. A medication delivery pen comprising:

a medication-containing cartridge assembly having a pierceably sealed distal end, an open proximal end having an array of threads, and a plunger

in sliding fluid tight engagement within said cartridge at a location distally of said array of threads; and

a pen body assembly having:

a housing with opposed proximal and distal ends, said distal end having an array of threads dimensioned and pitched for threaded engagement with said threads at said proximal end of said cartridge;

a lead screw having a proximal end disposed in said housing, a distal end projecting beyond said distal end of said housing for selective engagement with said plunger, and threads extending between said proximal and distal ends of said lead screw; and

a dose setting knob having two or more regions of operation, each region having a plurality of dosage indicia for a predefined range of dosage increments, said dose setting knob being used to move said lead screw distally in said pen body assembly a distance corresponding to the selected region of operation and dosage indicia.

2. The medication delivery pen of Claim 1, wherein said pen body assembly further includes an actuator button rotatably mounted on said dose setting knob, such that axial forces exerted on said actuator button generate movement of said lead screw distally in said pen body assembly and into said cartridge.

3. The medication delivery pen of Claim 1, wherein said dose setting knob defines specified distances of travel for said lead screw corresponding to selected doses of medication to be delivered.

4. The medication delivery pen of Claim 1, wherein said sealed end of said cartridge assembly comprises a pierceable elastomeric seal, and wherein said cartridge assembly further comprises needle mounting means adjacent said distal end of said cartridge assembly, said medication delivery pen further comprising a needle cannula assembly having a hub selectively engageable with the mounting means of said cartridge assembly and a double-ended needle having opposed proximal and distal points, said proximal point of said needle being dimensioned and disposed to pierce said seal upon engagement with said cartridge assembly.

5. The medication delivery pen of Claim 4, further comprising a plurality of needle cannula assemblies, each said needle cannula assembly being selectively engageable and disengageable from said cartridge assembly.

6. The medication delivery pen of Claim 1, wherein said lead screw of said pen body assembly includes a longitudinally extending groove therein, and wherein said cartridge assembly includes a tab for slidably engaging the lead screw, whereby said tabs prevent relative rotation between said lead screw and said cartridge assembly.

7. The medication delivery pen of Claim 1, wherein said pen body assembly includes a button and said dose setting knob includes a groove for receiving said button and thereby controlling movement of said lead screw distally in said pen body assembly and into said cartridge.

8. The medication delivery pen of Claim 7, wherein said groove on said dose setting knob has a different pitch in each region of said dose setting knob, wherein each pitch provides for different dosage increments.

9. The medication delivery pen of Claim 1, wherein said pen body assembly includes a driver selectively movable in proximal and distal directions in said pen body assembly housing, said driver connecting said dose setting knob to said lead screw.

10. The medication delivery pen of Claim 9, wherein said threads on said lead screw define a pitch substantially identical to said pitch of said threads on said distal end of said housing, said lead screw being axially movable in said housing in response to movement of said driver by said dose setting knob for selectively advancing said lead screw distances from said housing corresponding to selected doses of medication,

whereby the substantially identical pitches of said threads on said lead screw and on said housing enables said lead screw to move in said housing simultaneously with threaded engagement of said housing with said cartridge holder assembly.

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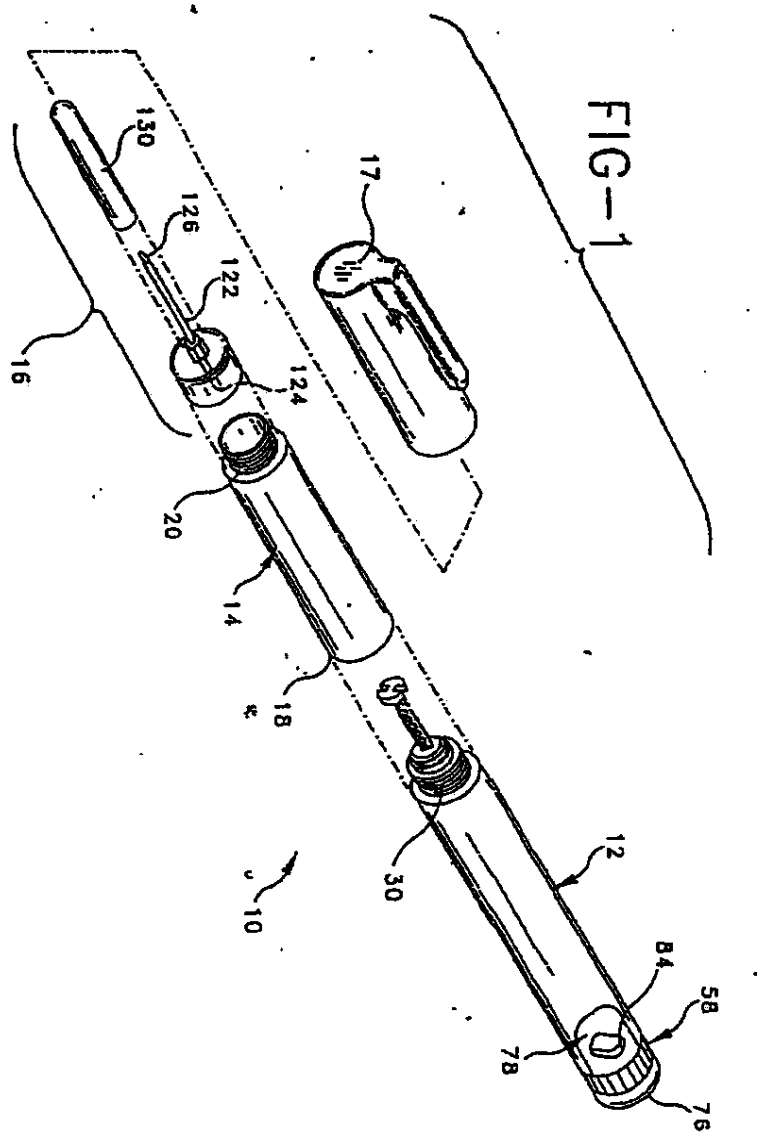

FIG-1

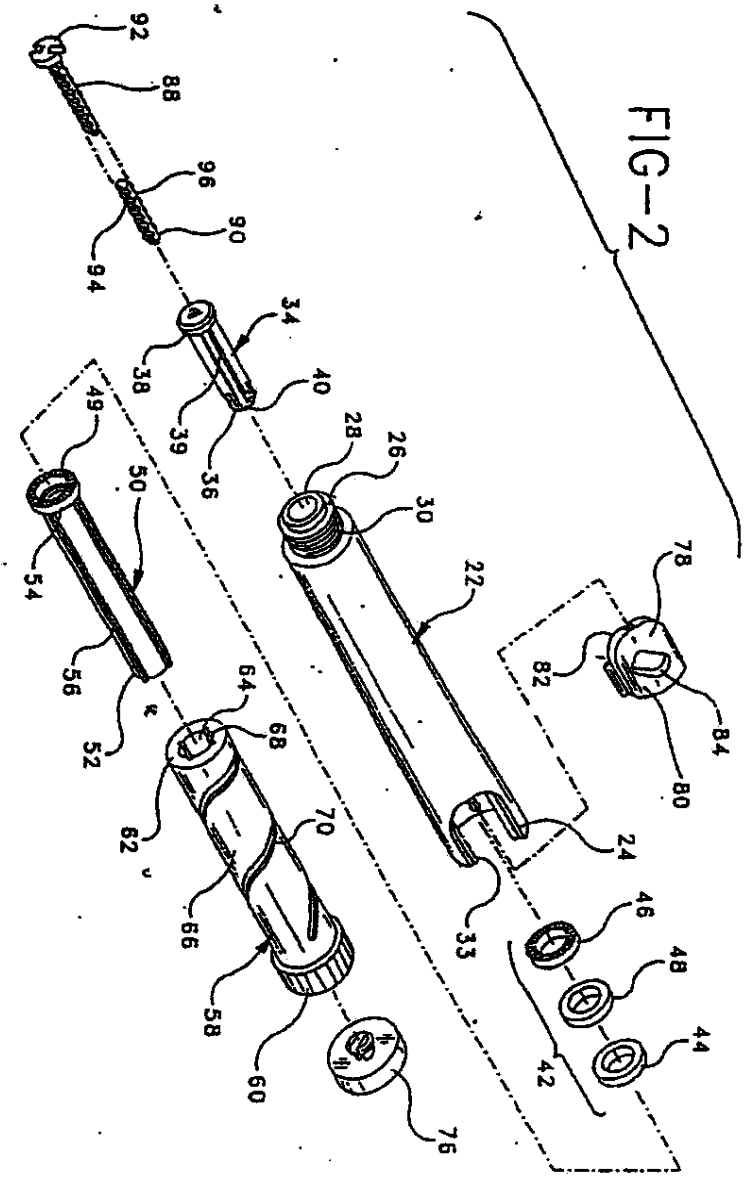
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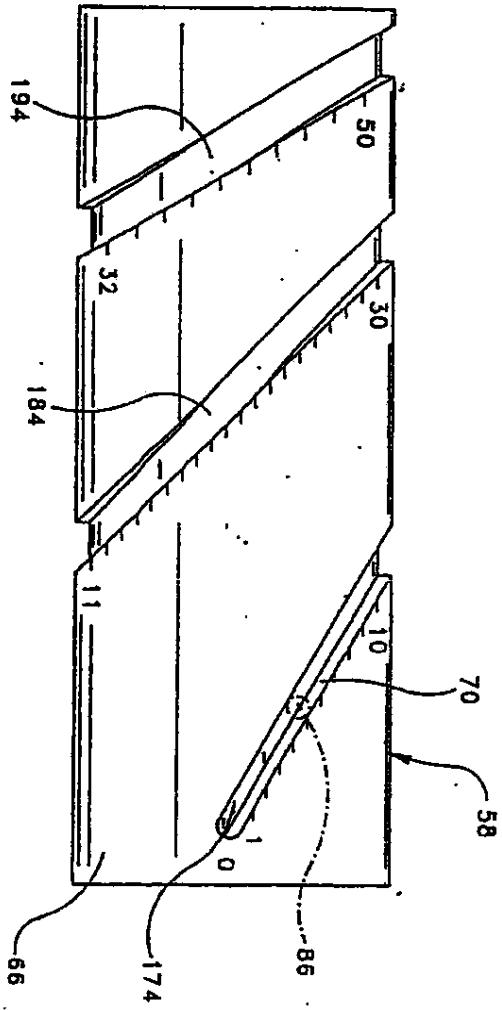
FIG-2

FIG-3



FIG—4

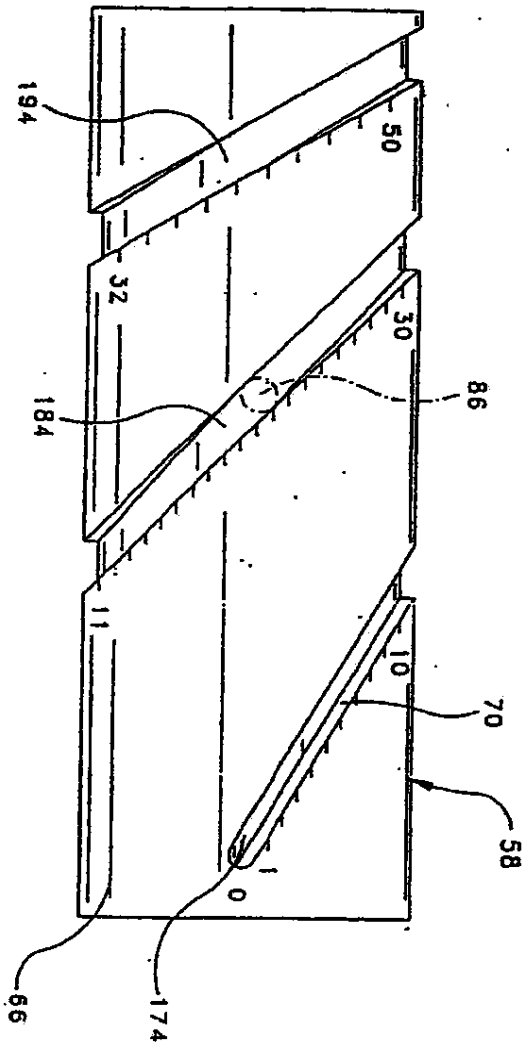
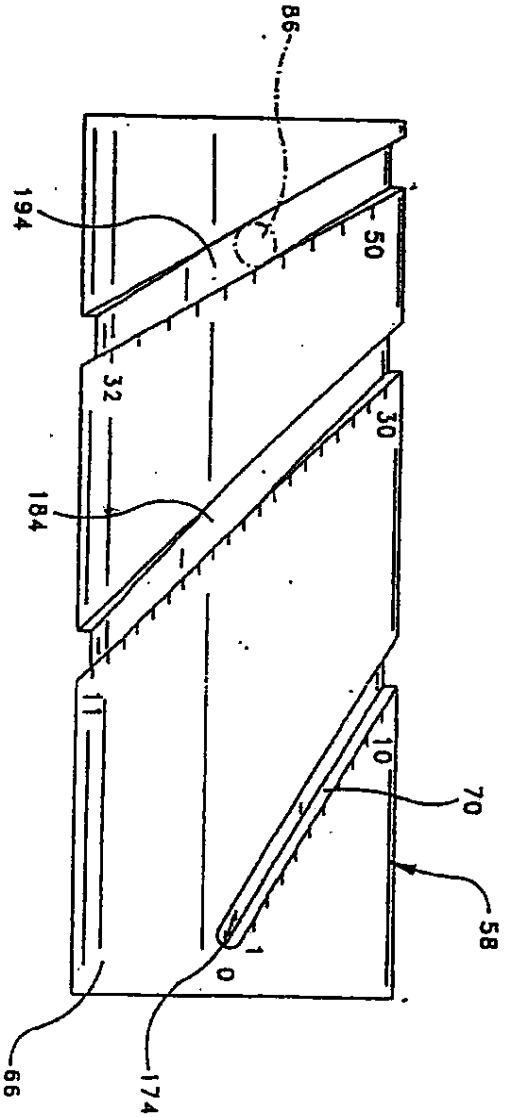


FIG-5



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(54) Title: SYRINGE SYSTEM

(57) Abstract

An insulin injection system comprises a pen shaped syringe with a cartridge containing insulin, and an injection needle. The needle is a G 30 needle and the insulin is a type which may freely flow through a G 30 needle. When the insulin is the type comprising suspended crystals the maximal dimension of any crystal is 15 µm.

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SYRINGE SYSTEM

The invention relates to syringes for injecting insulin and more specified pen-shaped syringes administering insulin doses from a cartridge in the pen syringe.

Diabetes is usually treated by the patient frequently injecting himself with an insulin dose which he adjusts each time according to his immediate need.

To make it less straining to the patient to prick himself several times a day, it is aspired to make the injections as painless as possible and to reduce the psychical malaise many people will feel if they have to pass a needle into their own body.

As the malaise seems to grow with the length and the thickness of the needle and the sensation of pain seems to be reduced when the needle is made thinner, a passable way seems to be to make the needle thinner and shorter. This line may, of course, only be followed to a certain extent, as the needle must have a length permitting the subcutaneous injection of the insulin and a thickness allowing the insulin to pass through the needle.

Whereas the acceptable minimum length of the needle is well defined, the lower limit for the thickness of the needle is more fluid. With a thinner needle it becomes more difficult to press the insulin out through the needle and the injections will take more time. A more relevant lower limit is set by the fact that by injecting insulin types appearing as suspended crystals, a sieving of the suspension may occur, and the suspension injected may consequently have a lower concentration than expected.

The thicknesses of needles are indicated by a "G" and a gauge number increasing with thinner needles. Thus, the outer diameter of a G 27 needle is 0.4 mm, of a G 28 needle 0.36 mm, and of a G 30 needle 0.3 mm. The wall thickness of the needles is typically 0.075 mm, so that a G 27 needle has a bore of 0.25 mm, whereas the bore of a G 30 needle is 0.15 mm.

Commonly, G 27 needles are used. However, according to Diabetes Forecast 1976; 29 page 27 problems are observed when G 27 needles and even thicker needles are used for injecting an insulin containing suspended crystals.

The problem is a clogging of the needle during injection, which clogging is due to the fact that crystals of e.g. Lente insulin having a size of 20 - 40 µm have a tendency to align themselves across the inside of the needle. This clogging is observed during injection, especially if this injection is carried out too slowly. It must be presumed that a similar clogging occurs during the filling of the syringe thus making the filling impossible or at least having the effect that some of the crystals are retained with the consequence that the suspension sucked into the syringe has a lower concentration then expected.

Whereas the trend goes towards the use of G 28 needles this is seen as close to the limit of what is possible. G 29 needles are seen as needles for disposable syringes for insulin, but G 30 needles have so far been deemed unusable for injection of an insulin suspension.

The present invention is based on the surprising recognition that needles thinner than G 29 may be used for injecting insulin.

The present invention is, thus, related to an insulin injection system comprising a pen shaped syringe having a cartridge with insulin and an injection needle, the system being characterized in that the needle is a G 30 needle and the cartridge contains an insulin type which may flow freely through a G 30 needle.

By the use of a pen shaped syringe with a cartridge the insulin will only have to pass the needle once, which in itself halves the risk of sieving. Further, the use of suspensions of insulin types having very short and needle shaped crystals totally eliminates the risk of bridging in a G 30 needle when no dimension of the insulin crystals exceeds 15 µm.

By closely binding a G 30 needle to a system further comprising a pen-shaped syringe, it may be ensured that a pen syringe equipped with a G 30 needle will always contain insulin of a type which may pass through the needle without any sieving effect.

The pen syringe may either be manufactured as a disposable device which is sold prefilled with the insulin or it may appear as a durable pen syringe so designed that it can only receive cartridges with insulin which may pass freely through a G 30 needle.

The needle may have attaching means cooperating with attaching means on the pen syringe for mounting the needle on the pen syringe, whereby the needle hub may be designed to only match with pen syringes of the system. Such attaching means may be a needle hub having a thread cooperating with a corresponding thread on the syringe.

The needle hub may have a central protrusion covering part of the length of the needle. Thereby, the length of the injection part of the needle is made shorter, which is advantageous as well from a psychological point of view as from a mechanical one. The protrusion makes visible only the part which should be inserted and it supports the thin and consequently more fragile needle.

With an injection part of the needle of 8 - 12 mm, it is avoided that the injections become intermuscular instead of subcutaneous. The needles may be manufactured in the same length as usual for thicker needles and the shorter injection part may be obtained by the hub protrusion covering a larger part than usual for the needle.

CLAIMS

1. An insulin injection system comprising a pen shaped syringe comprising a cartridge with insulin and an injection needle, characterized in that the needle is a G 30 needle and the cartridge contains an insulin type which may freely flow through a G 30 needle.

2. An insulin injection system according to claim 1, characterized in that the insulin in the cartridge has a maximal crystals size of 15 μm.

3. An insulin injection system according to claim 1 or 2, characterized in that the pen syringe is a disposable device prefilled with insulin.

4. An insulin injection system according to claim 1 or 2, characterized in that the pen syringe is a durable device designed to receive only cartridges containing insulin which may pass freely through a G 30 needle.

5. An insulin injection system according to any of the preceding claims, characterized in that the needle has attaching means for cooperation with attaching means on the pen syringe.

6. An insulin injection system according to claim 5, characterized in that the needle attaching means is a needle hub having a thread cooperating with a corresponding thread on the pen syringe.

7. An insulin injection system according to claim 6, characterized in that the needle hub has a central protrusion covering part of the length of the needle.

8. An insulin injection system according to claim 7, characterized in

that the length of the injection part of the needle is 8 - 12 mm.

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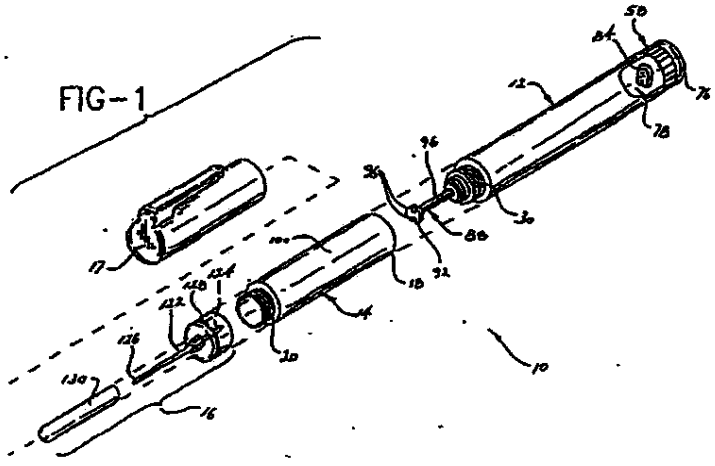
(54) Quick connect medication delivery pen

(57) A medication delivery pen is provided having a reusable pen body assembly and a disposable cartridge assembly that are threadedly engageable with one another. The disposable cartridge assembly includes a plunger and can releasably receive a needle cannula assembly. A portion of the pen body assembly projects into the cartridge holder assembly for driving the cartridge plunger distances that are selected in accordance with a desired dose of medication to be delivered. The cartridge holder assembly can be disassembled from the pen body assembly after the medication therein has been exhausted, and the used cartridge holder assembly may be discarded and replaced.

FIG-1



EP 0 688 571 A1

BACKGROUND OF THE INVENTION

1. Field of the Invention

The subject invention relates to medication delivery pens having a disposable cartridge holder assembly and a reusable pen body assembly removably mounted to the cartridge holder assembly for delivering selected doses of medication.

2. Description of Related Art

Hypodermic syringes are used to deliver selected doses of medication to patients. The prior art hypodermic syringe includes a syringe barrel having opposed proximal and distal ends. A cylindrical chamber wall extends between the ends and defines a fluid receiving chamber. The proximal end of the prior art syringe barrel is substantially open and receives a plunger in sliding fluid tight engagement. The distal end of the prior art syringe barrel includes a passage communicating with the chamber. A needle cannula may be mounted to the distal end of the prior art syringe barrel, such that the lumen of the needle cannula communicates with the passage and the chamber of the syringe barrel. Movement of the plunger in a proximal direction draws fluid through the lumen of the needle cannula and into the chamber. Movement of the plunger in a proximal-to-distal direction urges fluid from the chamber and through the lumen of the needle cannula.

Medication to be injected with the prior art hypodermic syringe often is stored in a vial having a pierceable elastomeric seal. Medication in the prior art vial is accessed by piercing the elastomeric seal with the needle cannula. A selected dose of the medication may be drawn into the chamber of the syringe barrel by moving the plunger a selected distance in a proximal direction. The needle cannula may be withdrawn from the vial, and the medication may be injected into a patient by moving the plunger in a distal direction.

Some medication, such as insulin is self-administered. The typical diabetes patient will require injections of insulin several times during the course of the day. The required dose of insulin will vary from patient to patient, and for each patient may vary during the course of the day and from day to day. Each diabetes patient will establish a regimen that is appropriate for his or her own medical condition and for his or her lifestyle. The regimen typically includes some combination of a slow or medium acting insulin and a faster acting insulin. Each of these regimens may require the diabetes patient to periodically self-administer insulin in public locations, such as places of employment or restaurants. The required manipulation of the standard prior art hypodermic syringe and vial can be inconvenient and embarrassing in these public environments.

Medication delivery pens have been developed to facilitate the self-administration of medication. One prior art medication delivery pen includes a vial holder into which a vial of insulin or other medication may be received. The vial holder is an elongate generally tubular structure with proximal and distal ends. The distal end of the prior art vial holder includes mounting means for engaging a double-ended needle cannula. The proximal end also includes mounting means for engaging a driver and dose setting apparatus as explained further below. A disposable vial for use with the prior art vial holder includes a distal end having a pierceable elastomeric seal that can be pierced by one end of a double-ended needle cannula. The proximal end of this prior art vial includes a plunger slidably disposed in fluid tight engagement with the cylindrical wall of the vial. This prior art medication delivery pen is used by inserting the vial of medication into the vial holder. A prior art pen body then is connected to the proximal end of the vial holder. The pen body includes a dose setting apparatus for designating a dose of medication to be delivered by the pen and a driving apparatus for urging the plunger of the vial distally for a distance corresponding to the selected dose.

The user of the pen mounts a prior art double-ended needle cannula to the distal end of the vial holder such that the proximal point of the needle cannula pierces the elastomeric seal on the vial. The patient then selects a dose and operates the pen to urge the plunger distally to deliver the selected dose. The dose selecting apparatus returns to zero upon injection of the selected dose with this prior art medication delivery pen. The patient then removes and discards the needle cannula, and keeps the prior art medication delivery pen in a convenient location for the next required medication administration. The medication in the vial will become exhausted after several such administrations of medication. The patient then separates the vial holder from the pen body. The empty vial may then be removed and discarded. A new vial can be inserted into the vial holder, and the vial holder and pen body can be reassembled and used as explained above.

The above described reusable medication delivery pen is effective and much more convenient for self-administration of medication than the typical hypodermic syringe and separate medication vial. However, the disassembly of the pen to remove empty medication vials and to insert new ones is an inconvenience. As a result, disposable pens have been developed. The prior art disposable medication delivery pen includes a vial of

insulin or other such medication permanently encapsulated therein. The patient need merely connect a double-ended needle cannula to the disposable pen for each administration of medication. The prior art disposable pen can be discarded when the supply of medication permanently encapsulated therein has been exhausted.

Disposable medication delivery pens offer certain conveniences to the patient who is required to self-administer medication. However, the dose selecting and driving mechanisms of prior art medication delivery pens are fairly complex devices that are costly to manufacture. Hence, a substantial cost penalty is associated with the convenience of using a disposable medication delivery pen.

SUMMARY OF THE INVENTION

The subject invention relates to a medication delivery pen having a disposable medication cartridge assembly that is selectively engageable with and disengageable from a reusable pen body assembly. The disposable medication cartridge assembly is an elongate generally cylindrical structure having opposed proximal and distal ends. The distal end of the disposable medication cartridge assembly includes needle mounting means for securely but releasably receiving a needle cannula assembly. The distal end may be characterized by a pierceable elastomeric seal that may be repeatedly and resealable pierced by the proximal end of a double-ended needle cannula. The proximal end of the disposable medication cartridge assembly includes body mounting means for securely but releasably mounting the disposable medication cartridge assembly to the reusable pen body assembly. The body mounting means may comprise an array of threads extending distally from the proximal end of the disposable medication cartridge assembly.

The disposable medication cartridge assembly further includes plunger means slidably disposed in fluid tight engagement therein. The plunger means may initially be disposed in a proximal position within the medication cartridge assembly and may be moved in a distal direction by a driver projecting from the pen body assembly. The disposable medication cartridge assembly further comprise anti-rotation means for preventing rotation of the driver.

The reusable pen body assembly of the subject invention comprises an array of mounting threads to enable threaded engagement of the reusable pen body assembly and the disposable medication cartridge assembly. An actuator button may be rotatably mounted on the proximal end of the pen body assembly. Thus, axial forces exerted on the actuator button will cause the pen body assembly to threadedly engage the disposable medication cartridge assembly.

The pen body assembly further includes a lead screw for selectively engaging the plunger of the disposable cartridge assembly and for urging the plunger of the disposable cartridge assembly in a distal direction. At least a portion of the lead screw may have driving threads engaged with other portions of the pen body assembly. This threaded engagement may be operative to achieve axial movement of the lead screw in response to axial forces exerted on the rotatable actuator button. The driving threads may define the same pitch and the same direction of generation as the mounting threads of the pen body assembly. As will be explained in greater detail below, this feature of the medication delivery pen facilitates the quick connection of the pen body assembly to the disposable medication cartridge assembly, and further assures a virtually automatic return of the lead screw to a start position each time a new disposable medication cartridge assembly is mounted to the pen body assembly. The lead screw may further be engageable with the anti-rotation means of the disposable cartridge assembly. Thus, relative rotation between the lead screw means and the disposable cartridge assembly is substantially prevented.

The pen body assembly further comprises a dose setting means for establishing and precisely controlling the amount of medication to be delivered in response to each actuation of the actuator button. The dose setting means may be any of several structures as described in greater detail below.

A disposable cartridge assembly that is filled with medication may be mounted to the pen body assembly by merely aligning the lead screw with the proximal end of the disposable cartridge assembly and exerting an axial force on the rotatable actuator button. The initial response to forces on the actuator button will cause the lead screw to move in a proximal direction toward its starting position, while the remaining portions of the pen body assembly move distally toward the disposable vial assembly. Further forces exerted on the actuator button will cause the mounting means of the pen body to engage the mounting means of the disposable cartridge assembly. Continued axial forces on the actuator will cause the mounting threads to engage the disposable cartridge assembly and will continue the proximal movement of the driver. The pen body assembly will be fully but releasably engaged with the disposable cartridge assembly at the same time that the driver is at its proximal extreme position and in condition to begin delivering selected doses of medication from the pen. Doses of medication can be dispensed as

needed over time. The disposable cartridge assembly can be removed and discarded when the medication therein has been exhausted, and a new disposable medication cartridge assembly may be mounted to the pen body assembly as described above.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded perspective view of the medication delivery pen of the subject invention.

Fig. 2 is an exploded perspective view of the pen body assembly of the medication delivery pen shown in Fig. 1.

Fig. 3 is an end view of the housing of the pen body assembly.

Fig. 4 is a cross-sectional view of the nut taken along line 4-4 in Fig. 2.

Fig. 5 is a cross-sectional view of the insert taken along line 5-5 in Fig. 2.

Fig. 6 is an end elevational view of the cartridge holder assembly.

Fig. 7 is a longitudinal cross-sectional view of the pen in a first partly assembled condition.

Fig. 8 is a cross-sectional view similar to Fig. 7, and showing the pen in a second partly assembled condition.

Fig. 9 is a cross-sectional view similar to Figs. 7 and 8, and showing the pen in a fully assembled condition.

Fig. 10 is a cross-sectional view similar to Fig. 9, and showing the assembled pen in condition to deliver a selected dose of medication.

Fig. 11 is a cross-sectional view similar to Fig. 10 and showing the pen after delivery of the selected dose.

DETAILED DESCRIPTION

A medication delivery pen in accordance with the subject invention is identified generally by the numeral 10 in Figs. 1 and 7-11. Medication delivery pen 10 includes a reusable pen body assembly 12, a disposable cartridge assembly 14, a needle cannula assembly 16 and a cap 17. Cartridge assembly 14 includes opposed proximal and distal ends 18 and 20 respectively. Proximal end 18 of cartridge assembly 14 is dimensioned and configured to threadedly engage pen body assembly 12, as explained further herein. Distal end 20 of cartridge assembly 14 is configured to securely but releasably engage needle cannula assembly 16.

The preferred embodiment of reusable pen body assembly 12 is illustrated in greater detail in Fig. 2. It is understood, however, that variations from this preferred embodiment may be provided, and are considered to be within the scope of the subject invention. Reusable pen body assembly 12 includes a generally cylindrical housing 22 having opposed proximal and distal ends 24 and 26, and a substantially hollow throughbore 28 extending axially therethrough. An array of external threads 30 extends proximally from distal end 26 for threaded engagement with proximal end 18 of cartridge holder assembly 14. Portions of hollow throughbore 28 of housing 22 adjacent distal end 26 are characterized by an array of clutch teeth 32, shown in Fig. 3, molded therein. Proximal end 24 of housing 22 is characterized by a cut-out 33 formed therein for receiving a window insert 78, as shown in Fig. 5 and explained further herein.

Pen body assembly 12 further includes a nut 34 having opposed proximal and distal ends 36 and 38 respectively. Exterior surface regions of nut 34 between proximal and distal ends 36 and 38, shown in Fig. 4, define a plurality of longitudinally extending splines 39. Proximal end 36 of nut 34 is characterized by a plurality of longitudinally extending resilient fingers 40 with enlarged ends that enable snap engagement of nut 34 into other portions of pen body assembly 12 as explained further herein. Distal end 38 of nut 34 is radially enlarged to limit axial movement of nut 34 into distal end 26 of housing 22. Thus, nut 34 is axially constrained within housing 22. However, the dimensions and configurations of nut 34 and housing 22 permit free relative rotation therebetween.

Pen body assembly 12 further includes a clutch assembly 42 mounted therein. Clutch assembly 42 includes a proximal clutch 44, a distal clutch 46 and an annular spring 48 biasingly engaged therebetween. Proximal and distal clutches 44 and 46 each are configured for non-rotatable engagement over splines 39 of nut 34. Distal clutch 46 includes an array of distally facing saw teeth dimensioned, disposed and configured for engagement with teeth 32, shown in Fig. 3, on the interior of housing 22, such that distal clutch 46 can rotate only in one direction relative to housing 22. Proximal clutch 44 includes an array of proximally facing teeth which are also configured for unidirectional rotation as explained further herein.

Pen body assembly 12 further includes a generally cylindrical driver 50 having opposed proximal and distal ends 52 and 54. Driver 50 is slidably inserted into housing 22 of pen body assembly 12 such that distal end 54 of driver 50 is snap fit over the enlarged ends of resilient fingers 40 at proximal end 36 of nut 34. This snap fit engagement prevents axial movement between nut 34 and driver 50, but permits free relative rotational movement within housing 22. Distal end 54 of driver 50 is also characterized by an array of saw teeth 49 that engage with the saw teeth on proximal clutch 44. Outer surface regions of driver 50 are characterized by splines 56 extending radially outwardly

thereon and along a substantial portion of the length of driver 50.

Pen body assembly 12 further includes a dose knob 58 which is a hollow generally cylindrical structure having opposed proximal and distal ends 60 and 62 and opposed inner and outer surfaces 64 and 66. Inner surface 64 is characterized by longitudinally extending grooves 68 which are disposed and dimensioned for engagement with splines 56 on driver 50. More particularly, dose knob 58 is spline mounted over driver 50 within housing 22 of pen body assembly 12. Thus, axially extending grooves 68 in dose knob 58 engage splines 56 of driver 50 to prevent relative rotation therebetween, but permitting relative axial movement. Outer surface 66 of dose knob 58 is characterized by a groove 70 that includes a linear component 72 and a helical component 74, which connects opposed ends of linear component 72. Portions of outer surface 66 adjacent helical component 74 of groove 70 are provided with dosage indicia to define dose amounts corresponding to different positions along groove 70 as explained further herein. Proximal end 60 of dose knob 58 is characterized by a gnarled exterior surface to facilitate manipulation for setting a selected dose. An actuator button 76 is snapped in to engagement with proximal end 60 of dose knob 58 to permit relative rotation therebetween.

An insert 78, shown in Figs. 2 and 5, is snapped into engagement with cut-out 33 in the proximal end 24 of housing 22. Insert 78 includes opposed inner and outer surfaces 80 and 82 and a window 84 extending therebetween. Inner surface 80 of insert 78 includes a button 86 on an interior face which is dimensioned and disposed to engage in groove 70 of dose knob 58. Button 86 and window 84 are disposed to enable the indicia on dose knob 58 to be visible through window 84.

Pen body assembly 12 further includes a lead screw 88 with opposed proximal and distal ends 90 and 92 and an array of external threads 94. External threads 94 are characterized, however, by a pair of opposed axially extending grooves 96 which extend from distal end 92 substantially to the proximal end 90. Threads 94 are engaged in nut 34, such that proximal end 90 of lead screw 88 is within housing 22 and distal end 92 projects distally beyond housing 22. Threads 94 on lead screw 88 have exactly the same pitch and the same hand as threads 30 on distal end 26 of housing 22.

Pen body assembly 12 is assembled by placing nut 34 into housing 22 from distal end 26. Clutch assembly 42 then is mounted over splines 39 on nut 34. Driver 50 is then inserted into proximal end 24 of housing 22, and is urged sufficiently in a distal direction for snap fit engagement with nut 34. In this snapped engagement, the saw teeth of distal clutch 46 will be secured in engagement with teeth 32 of housing 22, and the saw teeth of proximal clutch 44 will be engaged with saw teeth 49 at distal end 54 of driver 50. Spring 48 will maintain constant selected pressure between these interengaged saw teeth. Insert 78 then is positioned over dose knob 58 such that button 86 of insert 78 is engaged in the axial return track 72 of groove 70 in dose knob 58. The temporarily assembled insert 78 and dose knob 58 then are urged into housing 22. Lead screw 88 then is threaded into nut 34, and actuator button 76 is snapped into engagement with proximal end 60 of dose knob 58.

Cartridge assembly 14, shown in Figs. 1 and 6-11, includes a molded housing 100 which extends from proximal end 18 to distal end 20 of cartridge assembly 14, as noted above. Housing 100 includes a mounting cavity 102 extending inwardly from proximal end 18. Mounting cavity 102 is characterized by an array of internal threads 104 for threaded engagement with external threads 30 on distal end 26 of housing 22. The distal end of mounting cavity 102 is defined by anti-rotation tabs 106 which are dimensioned to slidably engaged in slots 96 of lead screw 88. Thus, lead screw 88 can slidably move relative to anti-rotation tabs 106, but is prevented from rotating relative to tabs 106.

Cartridge holder assembly 14, as shown in Figs. 7-11, further includes a medication cartridge 108 securely retained in housing 100 between tabs 106 and distal end 20 of cartridge assembly 14. Medication cartridge 108 includes an open proximal end 110 and a distal end 112 having a pierceable elastomeric seal 114 securely mounted thereto. A cap 116 extends between housing 100 and cartridge 108 for securely and permanently holding medication cartridge 108 in housing 100. A plunger 118 is disposed in sliding fluid tight engagement in cartridge 108. As shown in Figs. 7-11, plunger 118 initially is disposed substantially adjacent proximal end 110 of medication cartridge 108. Portions of cartridge 108 between plunger 118 and seal 114 are filled with a medication 120, such as insulin.

Needle cannula assembly 16 includes a double ended needle cannula 122 having opposed proximal and distal points 124 and 126, respectively, and a lumen extending axially therebetween. A mounting hub 128 is engaged on needle cannula 122 and is removably engageable with cap 116 of cartridge holder assembly 14. The relative location of mounting hub 128 ensures that proximal point 124 of needle cannula 122 will pierce seal 114 when mounting hub 128 is engaged with cap 116. Needle cannula assembly 16 further includes a shield 130 removably mounted thereon for protecting against accidental needle sticks until immediately prior to use of pen 10.

As noted above, pen body assembly 12 is reusable, and cartridge holder assembly 14 is disposable. More particularly, cartridge 108 in cartridge holder assembly 14 will contain a volume of medication 120 sufficient for administration of several doses. After exhaustion of the medication 120, cartridge holder assembly 14 will be threadedly disengaged from pen body assembly 12 and discarded. A new cartridge holder assembly 14 may then be mounted to the reusable pen body assembly 12. To effect the mounting of a new cartridge holder assembly 14 to the reusable pen body assembly 12, the patient need merely align slots 96 at distal end 92 of lead screw 88 with tabs 106 at proximal end 18 of cartridge holder assembly 14. Distal end 92 of lead screw 88 is then advanced distally into cartridge holder assembly 14 until distal end 92 of lead screw 88 engages plunger 118, as shown in Fig. 7. Assembly continues by merely exerting axial forces on thumb swivel 76 and on cartridge holder assembly 14. Additionally, friction between plunger 118 and cartridge 108 and fluid forces exerted by medication 120 and seal 114 will prevent axial advancement of lead screw 88 beyond the position depicted in Fig. 9 during assembly. Additionally, the splined engagement of distal clutch 46 with nut 34 and the engagement of the teeth on distal clutch 46 with the corresponding teeth 32 on housing 22 prevents independent rotation of nut 34 during this initial mounting of reusable pen body assembly 12 with a new disposable cartridge assembly 14. Thus, axial forces exerted on thumb swivel 76 will cause cartridge housing 100 to threadedly advance along threads 94 of lead screw 88.

After sufficient axial advancement, threads 30 at distal end 26 of pen body housing 22 will engage internal threads 104 at proximal end 18 of cartridge holder assembly 14, as shown in Fig. 8. As noted above, external threads 30 at distal end 26 of housing 22 have exactly the same pitch and hand as threads 94 on lead screw 88. Hence, further axial forces exerted on thumb swivel 76 will cause the simultaneous threaded advancement of housing 22 along lead screw 88 and into cavity 102 at proximal end 18 of cartridge holder assembly 14. Thus, because of their identical pitches, lead screw 88 will move proximally relative to pen body housing 22, while pen body housing 22 and cartridge holder assembly 14 are approaching their fully seated and threaded condition depicted in Fig. 9.

The assembled reusable pen body assembly 12 and cartridge assembly 14 may be stored until a selected dose of medication is required. Just prior to use, a needle cannula assembly 16 may be threadedly engaged to distal end 20 of cartridge assembly 14. This threaded engagement will cause proximal tip 124 of needle cannula 122 to pierce seal 114 and provide communication with medication 120. Shield 130 may then be removed.

A desired dose of medication 120 may be set by rotating dose knob 58 until indicia corresponding to the desired dose appears in window 84 of insert 78. The engagement of button 86 on insert 78 in helical portion 74 of groove 70 in dose knob 58 will cause a threaded retraction of dose knob 58 relative to housing 22 of reusable pen body assembly 12. This threaded retraction of dose knob 58 will cause a simultaneous rotation of driver 50 splined thereto. However, nut 34 will not rotate because the saw teeth on distal clutch 46 and saw teeth 32 on interior portions of housing 22 are locked to prevent rotation in that direction. Proximal clutch 44 is splined to nut 34, and hence also will not turn. However, saw teeth 49 at distal end 54 of driver 50 are shaped to allow rotation relative to proximal clutch 44, but provide an audible click for each unit of medication in the selected dose. This is helpful for visually impaired patients who may be required to set doses and administer insulin or other medication to themselves. Annular spring 48 contributes to the engagement that provides these audible clicking sounds.

When the desired dose is set, as shown in Fig. 10, injection is achieved by merely pushing on actuator button 76. This causes dose knob 58 to turn about helix 74 relative to pen body housing 22, and driver 50 rotates through the same number of degrees. This rotation is opposite to the rotation generated by the dose setting procedure, and the rotational freedom of the clutch assembly 42 is reversed. Thus, as driver 50 turns the previously clicking proximal clutch 44 is locked to and turns with driver 50. This driving movement of proximal clutch 44 causes a corresponding rotational movement of nut 34 because of the splined engagement therebetween. Distal clutch 46 is now free to rotate against saw teeth 32 on housing 22, and makes an audible clicking indication during injection of medication.

Rotation of lead screw 88 is prevented by tabs 106 unitarily molded with housing 100 of cartridge holder assembly 14. Therefore, as nut 34 rotates under the driving action of proximal clutch 44 and driver 50, lead screw 88 will be advanced axially into cartridge holder assembly 14. This axial advancement of lead screw 88 causes distal end 92 thereof to urge plunger 118 distally into cartridge 108, and hence causes medication 120 to be injected through needle cannula 122. Injection will be terminated when proximal end 60 of dose knob 58 engages against proximal end 24 of pen body housing 22, as shown in Fig. 11.

Upon completion of the injection, needle cannula assembly 16 may be disengaged from car-

tridge holder assembly 14 and safely discarded. Cap 17 may be mounted over cartridge holder assembly 14, and pen 10 may be stored or carried in a convenient location until the next dose of medication is required. A subsequent dose of medication will be set in exactly the manner as described above. However, for such a subsequent dose, lead screw 88 and plunger 118 will be in a partly advanced position as a starting point. Dose setting and injections can be carried out until all of medication 120 has been used. Cartridge holder assembly 14 may then be threadedly disengaged from pen body assembly 12, and slidably separated from lead screw 88. The separated cartridge holder assembly may then be discarded and replaced as described above.

While the invention has been described with respect to a preferred embodiment, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims. In particular, the reusable pen body assembly may have other driving and/or clutch mechanisms. Additionally, different means for preventing and/or enabling rotation during the dose setting and injection phases may be provided. Similarly, other means for mounting needle cannula to the cartridge assembly may be provided. These various optional constructions will be apparent to those skilled in the art after having read the subject disclosure.

Claims

1. A medication delivery pen comprising:

a disposable medication-containing cartridge having a pierceably sealed distal end and an open proximal end having an array of threads, a plunger in sliding fluid tight engagement within said cartridge at a location distally of said array of threads;

a reusable pen body assembly having a housing with opposed proximal and distal ends, said distal end having an array of threads dimensioned and pitched for threaded engagement with said threads at said proximal end of said cartridge, a lead screw having a proximal end disposed in said housing, a distal end projecting beyond said distal end of said housing for selective engagement with said plunger, and threads extending between said proximal and distal ends of said lead screw and defining a pitch substantially equal to said pitch of said threads at said distal end of said pen body assembly, said pen body assembly further comprising driver means for moving said lead screw distally in said pen body assembly selected amounts, whereby said lead screw is movable in a proximal direction in said pen body assembly as said pen body assembly is threadedly moved in a distal direction into engagement with said cartridge.

2. The medication delivery pen of Claim 1, wherein said pen body assembly further includes an actuator button rotatably mounted on said driver means, such that axial forces exerted on said actuator button simultaneously generate movement of said lead screw in a proximal direction in said pen body assembly and threaded engagement of said pen body assembly distally into said cartridge.

3. The medication delivery pen of Claim 1, wherein said lead screw includes at least one anti-rotation groove extending axially therealong, said cartridge including tab means for slidably engaging in said anti-rotation groove of said lead screw for preventing relative rotation between said lead screw and said cartridge.

4. The medication delivery pen of Claim 3, wherein said cartridge includes a housing unitarily molded from a plastic material, said tab being a unitary portion of said housing.

5. The medication delivery pen of Claim 1, wherein said cartridge defines a mounting cavity adjacent said proximal end thereof, said threads of said cartridge defining internal threads in said mounting cavity, said distal end of said pen body assembly being dimensioned for threaded engagement in said mounting cavity of said cartridge.

6. The medication delivery pen of Claim 1, wherein said pen body assembly comprises dose setting means for defining specified distances of travel for said lead screw corresponding to selected doses of medication to be delivered.

7. The medication delivery pen of Claim 1, wherein said sealed end of said cartridge comprises a pierceable elastomeric seal, and wherein said cartridge further comprises needle mounting means adjacent said distal end of said cartridge, said medication delivery pen further comprising a needle cannula assembly having a hub selectively engageable with the mounting means of said cartridge and a double-ended needle having opposed proximal and distal points, said proximal point of said needle being dimensioned and disposed to pierce said seal upon engagement with said cartridge.

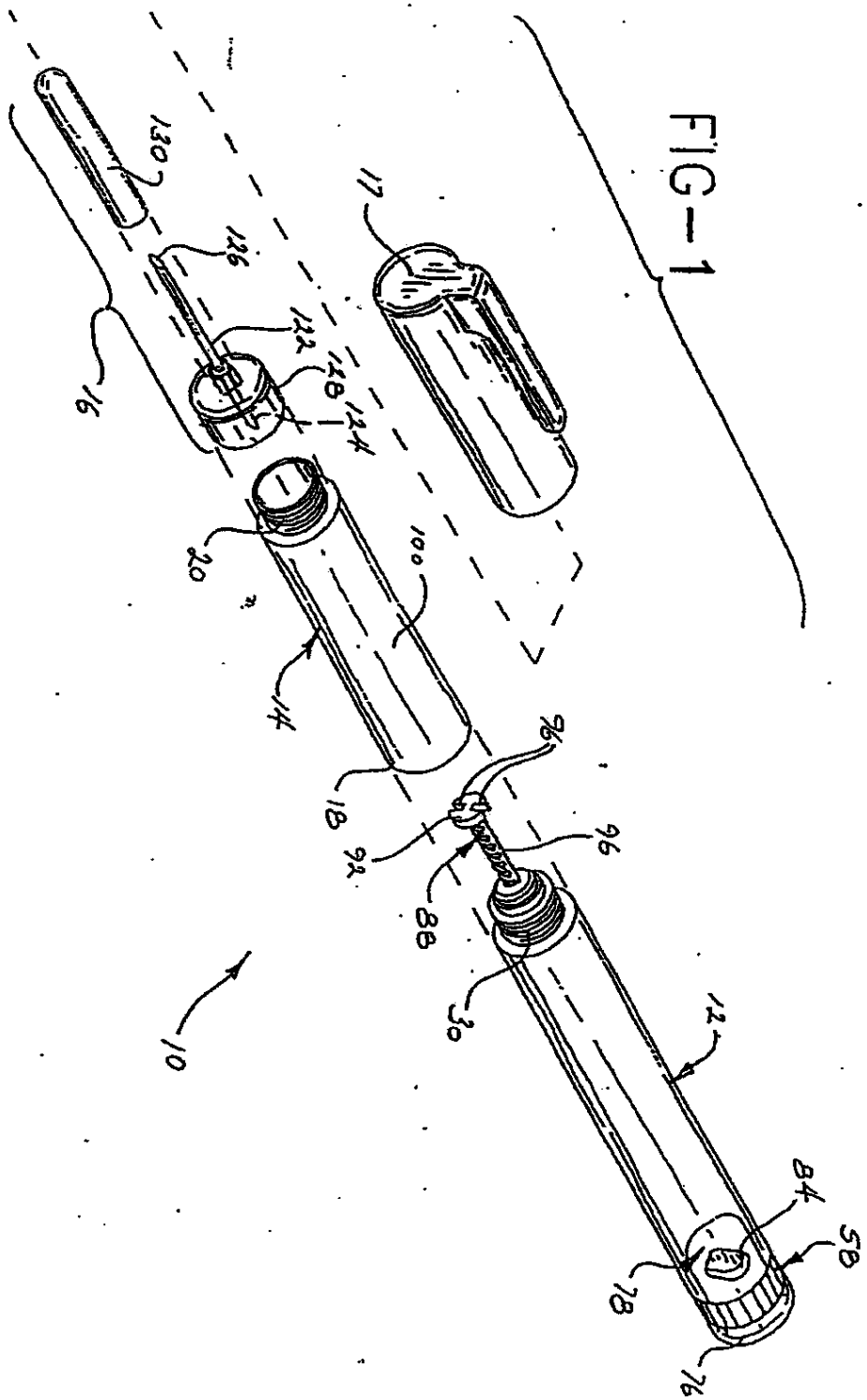
8. A reusable medication delivery pen system comprising:

a plurality of disposable cartridge holder assemblies, each said disposable cartridge holder assembly including an elongate cartridge housing having opposed proximal and distal ends, an elongate medication-containing cartridge mounted in said cartridge housing, said cartridge having a sealed distal end and an open proximal end, a plunger slidably disposed in fluid tight engagement in said cartridge, medication disposed in said cartridge intermediate said plunger and said seal, said proximal end of said housing of said cartridge holder assembly defining an array of threads;

a reusable pen body assembly having a pen body housing with opposed proximal and distal ends, said distal end of said pen body housing having an array of threads defining a pitch for threaded engagement with said threads at said proximal end of any of said cartridge housing, said pen body assembly having a driver selectively movable in proximal and distal directions in said pen body housing and dose setting means selectively adjustable for controlling amounts of movement of said driver, a lead screw having opposed proximal and distal ends, said distal end of said lead screw being selectively engageable with the plunger of any of said cartridge holder assemblies, said lead screw further comprising an array of external threads thereon threadedly engaged for rotation in said body housing, said threads on said lead screw defining a pitch substantially identical to said pitch of said threads on said distal end of said pen body housing, said lead screw being axially movable in said pen body housing in response to movement of said driver for selectively advancing said lead screw distances from said housing corresponding to selected doses of medication, whereby the substantially identical pitches of said threads on said lead screw and on said pen body housing enables said lead screw to move proximally in said body housing simultaneously with threaded engagement of said body housing with said cartridge holder housing.

9. The medication delivery pen system of Claim 8, further comprising a plurality of needle cannula assemblies, each said needle cannula assembly being selectively engageable and disengageable from each of said respective cartridge holder assemblies.

10. The medication delivery pen system of Claim 8, wherein the lead screw of said reusable pen body assembly includes a longitudinally extending groove therein, and wherein each said cartridge housing includes a tab for slidably engaging the lead screw, whereby said tabs prevent relative rotation between said lead screw and said cartridge holder assembly.



FIG—1

FIG-2

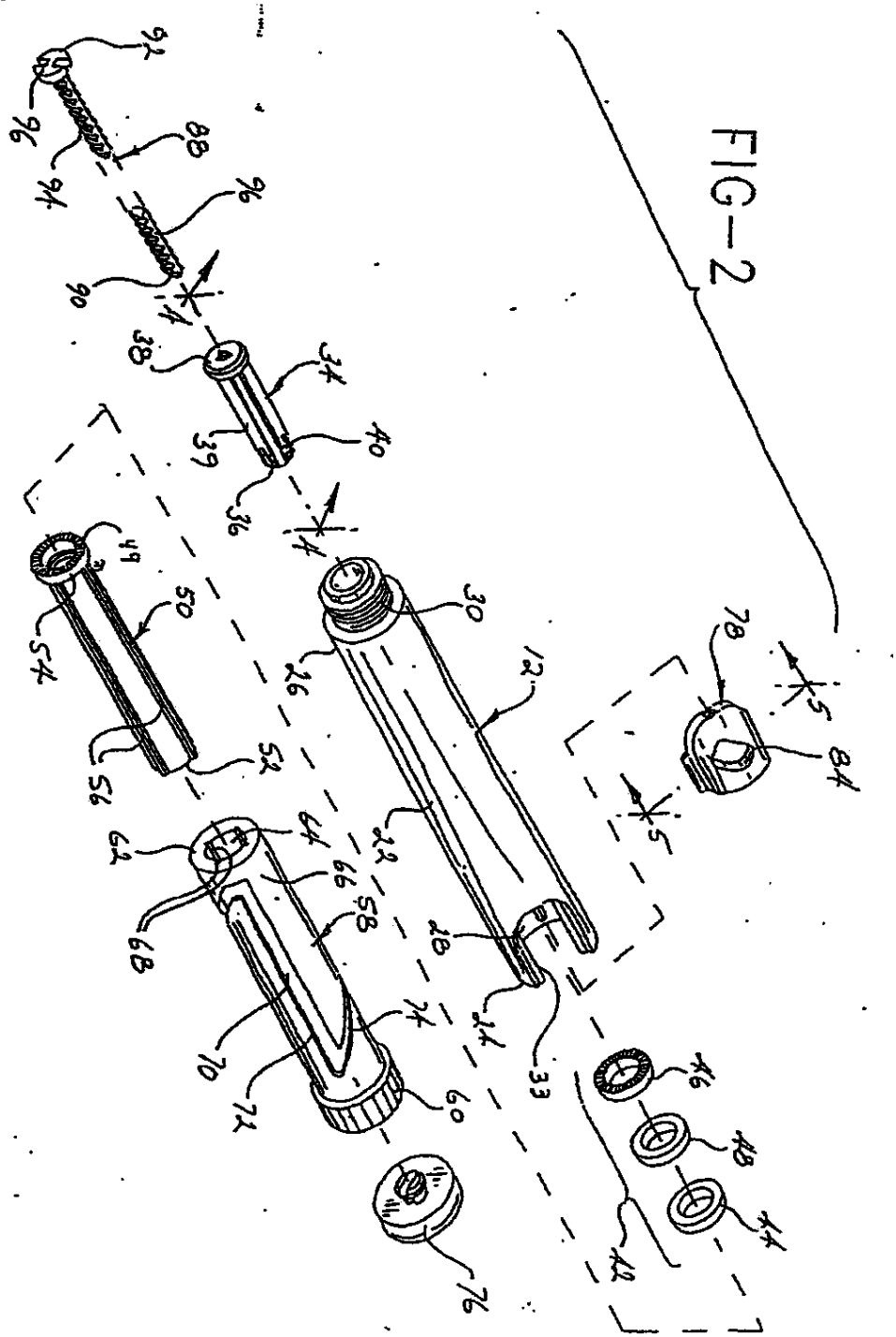

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FIG-3

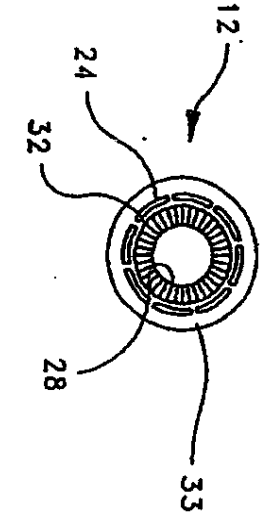

FIG-5

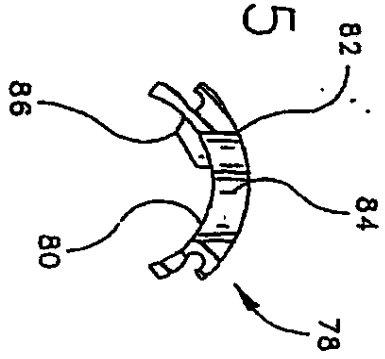

FIG-4

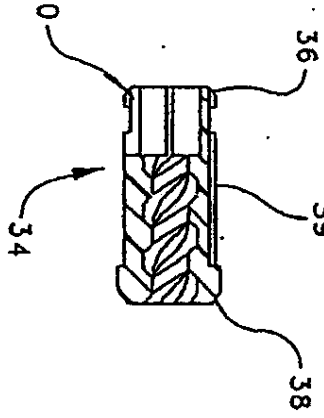

FIG-6

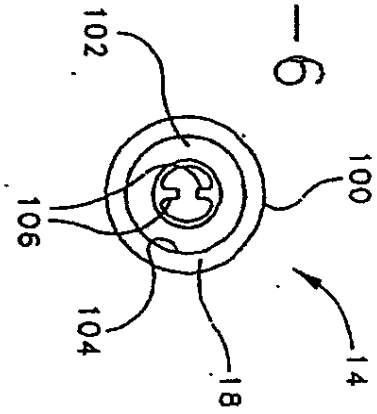

FIG-7

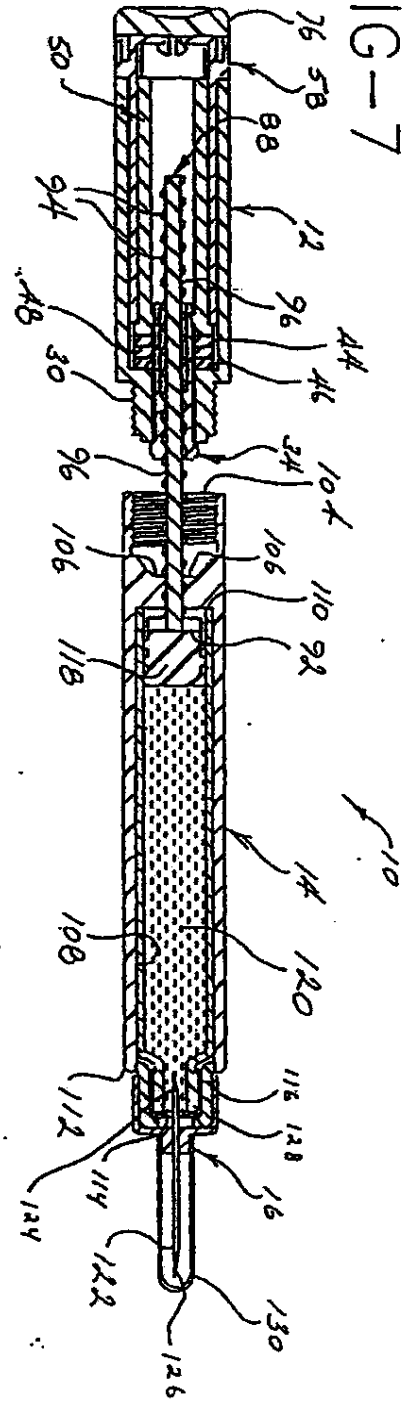
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FIG-8

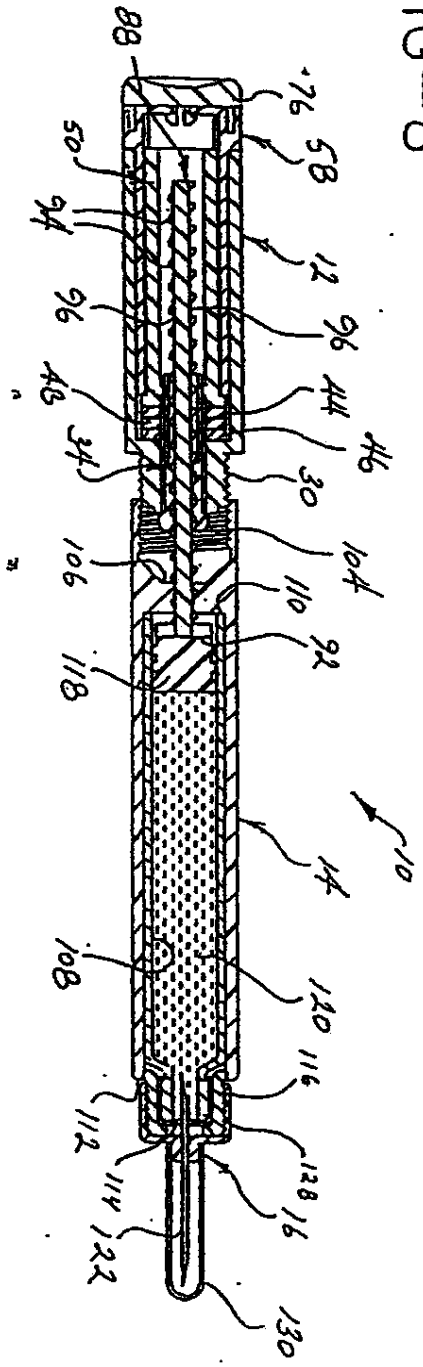
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FIG-9

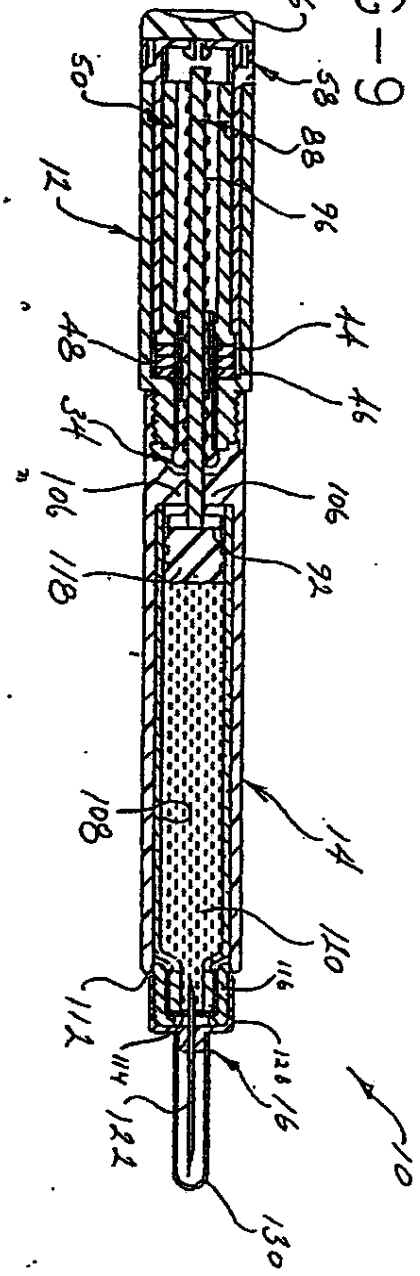
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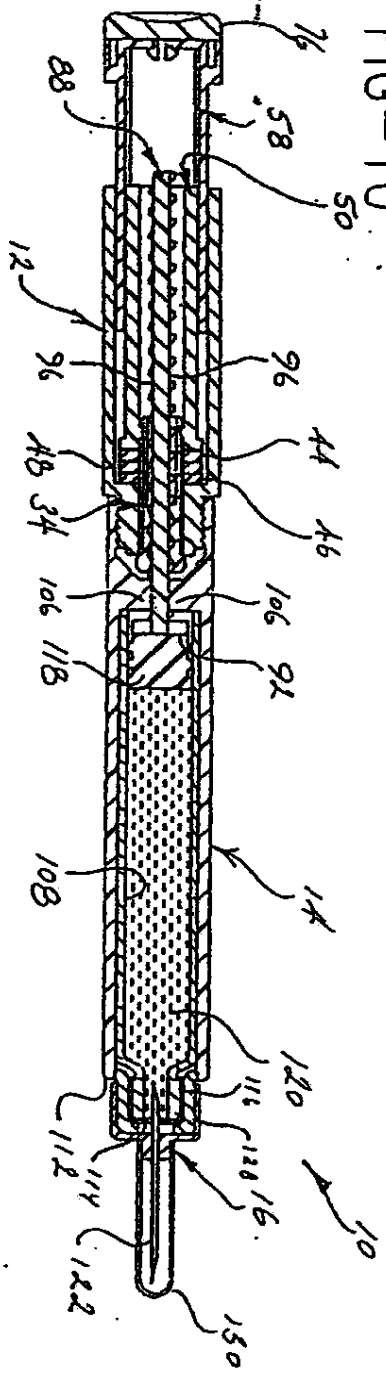
FIG-10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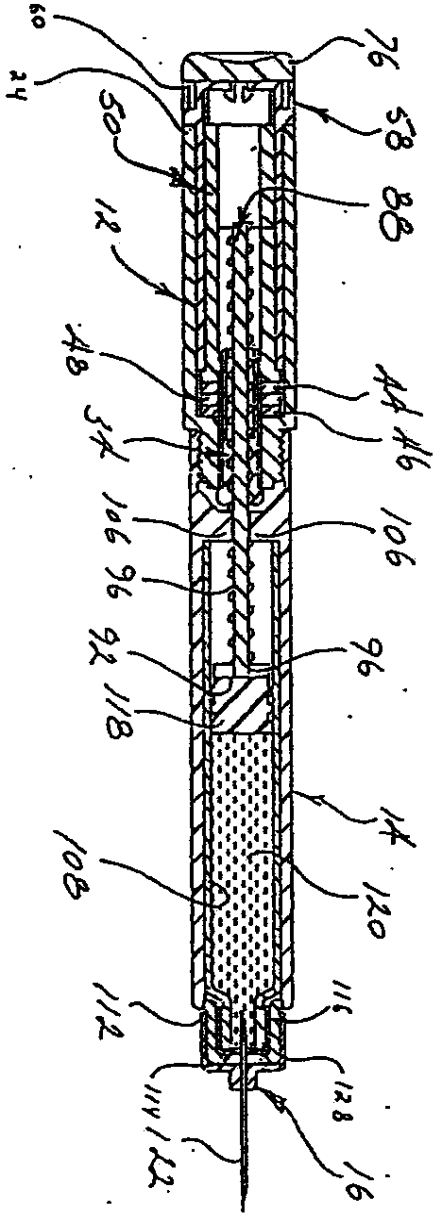
FIG—11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European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 95 30 3894

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X Y	EP-A-0 450 905 (ELI LILLY AND COMPANY) * column 2, line 19 - line 34 * * column 5, line 44 - column 6, line 13; figures 1-3,5,8,9 *	1-3,6-10 5	A61M5/315
Y	EP-A-0 268 191 (WILHELM HASELMEIER GMBH & CO.) * figures 1-4 *	5	
A	US-A-4 973 318 (HOLM ET AL.) * abstract; figures 1-5,13,14,18 *	1-10	
A	EP-A-0 554 995 (BECTON DICKINSON AND COMPANY)		
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	20 September 1995	Michels, N

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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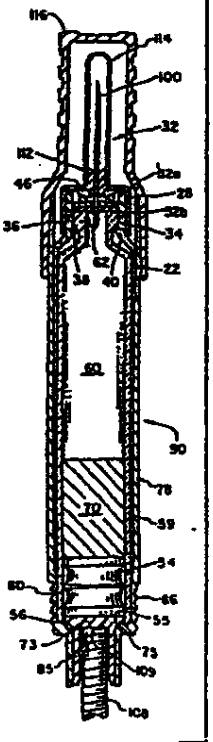
(54) Title: CARTRIDGE ASSEMBLY FOR A LYOPHILIZED COMPOUND FORMING A DISPOSABLE PORTION OF AN INJECTOR PEN AND METHOD FOR SAME

(57) Abstract

A cartridge assembly (90) for holding a lyophilized product, forming a disposable portion of a pen injector (104), includes a cylindrical glass cartridge (58) adapted to receive the product, a closure cap (20), a cartridge case (76), and a plunger mechanism. The closure cap (20) is adapted to retain an elastomeric disc seal (52) during lyophilization and includes diametrically opposed ledges (38, 40). The closure cap (20) and seal (52) are adapted to cover a neck portion of the ampule (58), the neck portion having on its end a radially extending circumferential flange (62). The ledges (38, 40) of the closure cap (20) and the flange (62) of the neck portion allow the closure cap (20) to remain open during lyophilization, oxygen purge and nitrogen overlay. An oval-shaped indentation formed on the inside of the closure cap (20) aids in snapping the closure cap (20) about the flange (62) without crimping to retain the closure cap (20) underneath the flange (62). Reconstitution of the lyophilized drug is accomplished without foaming by use of an obliquely angled connector (30) which causes the diluent to indirectly impinge on the drug. The injection pen (104) and cartridge assembly (90) cooperate such that the length of travel of the plunger rod (108) during retraction is less than the axial length of a recess (107) in the rod tip (73).



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CARTRIDGE ASSEMBLY FOR A LYOPHILIZED COMPOUND FORMING A DISPOSABLE PORTION OF AN INJECTOR PEN AND METHOD FOR SAME

The present invention relates to the sealing and dispensing of pharmaceuticals and, more particularly to the sealing and dispensing of a lyophilized drug in a cartridge assembly.

In current technology, drugs or compounds manufactured for various injections are generally encapsulated in sterile glass cartridges. The glass cartridges characteristically have a sealed end with the other end of the cartridge generally having a restricted opening in the form of a neck having a circumferential flange. The opening can be closed off with a rubber membrane held into place with an aluminum seal crimped therearound. Where the drug or compound is to be later dispensed either directly from the cartridge or in a dispensing device such as a pen dispenser, the cartridge includes at the end opposite the restricted opening, an open end generally having a rubber plunger closing the open end. The rubber plunger also acts as a piston to force the drug or compound contained within the cartridge out of the restricted opening into which there has generally been inserted a cannula, by action of a plunger rod exerting axial pressure upon the rubber plunger.

Cartridges for use with dispenser devices or pens as described above are generally known in the prior art. U.S. Patent 4,936,833 Sams, shows a typical glass cartridge having an open end with a plunger therein, and an opposite end including a restricted opening sealed with a rubber membrane and crimped metal collar. The cartridge is insertable into a housing forming a part of a dispenser pen, with a cap for receiving a two ended cannula. Typical of these device are U.S. Patent 4,883,472 Michel, and U.S. Patent 4,973,318 Holm et al.

Lyophilized drugs or compounds are currently being utilized as the basis for injectionable compounds, such as

human growth hormone (HGH), insulin, and the like. Lyophilization is the rapid freezing of a material at a very low temperature followed by rapid dehydration by sublimination in a high vacuum. The lyophilized compound is generally contained in a glass vial or cartridge. However, the process described above is not suitable for lyophilized compounds which are moisture and oxygen sensitive. When the moisture is removed from the compound during lyophilization, the oxygen in the glass cartridge containing a lyophilized drug must be replaced with nitrogen after the lyophilization process. This step of replacing the oxygen with nitrogen is termed nitrogen overlay and is accomplished within the lyophilizing chamber (freeze dryer).

One technique is to lyophilize the drugs or compounds in rubber stoppered glass vials. During lyophilization of the compounds in the glass vials, the rubber stopper used to close the vial is partially seated in the neck of the vial. The moisture which is removed from the compound during lyophilization is vented out through grooves or slots formed in the rubber stopper. As a general method of closing the vials, the shelves of the lyophilization chamber vertically move together to press the rubber stopper down into the vial, until the vents in the stopper are well inside the neck opening of the vial. An aluminum seal is then crimped about a flange on the neck of the vial.

The use of aluminum as a crimping seal for the rubber stopper is not, however, preferred due to the possibility of aluminum dust or particles contaminating the compound during the initial crimping, reconstitution, or administration processes. In addition, such processes as above are not well suited for efficient lyophilization.

Thus, it is desired to eliminate the aluminum crimping seal as well as provide an easier method of assuredly allowing lyophilization of a compound and sealing the same.

In order to administer a lyophilized compound, it is necessary to reconstitute the compound prior to administration with a suitable diluent. Reconstitution is accomplished by using a syringe with a needle to withdraw the diluent from a separate vial and inject it into the vial containing the lyophilized compound. The vial containing the lyophilized compound is placed in a holder during reconstitution. Because the cartridge is filled with the lyophilized compound and nitrogen, addition of the diluent produces extra pressure within the cartridge which creates the possibility of forcing the plunger out of the cartridge. Having the plunger forced out of the cartridge during reconstitution would undesirably result in a total loss of the compound.

During reconstitution, the diluent injected from the syringe into the cartridge directly impinges upon the lyophilized compound which causes the lyophilized compound to foam. The foam undesirably creates extra head space within the cartridge such that the proper amount of diluent is not mixed with the compound, resulting in an improper diluent to compound ratio. In order to alleviate this, one must wait for the foam to subside.

A patient needle is then attached to the disc sealed end of the cartridge which thus allows the compound to be injected. Current injector pens dispense a selectable amount of drug depending on the required dosage. A plunger mechanism, including a plunger rod, pushes against the plunger in the cartridge. After each injection, the plunger mechanism and plunger rod retract during a resetting function of the injector pen. However, complete disengagement of the plunger rod from the plunger mechanism during retraction is highly undesirable, and can render the injector pen inoperative.

Because of the expanding use of pen dispensers or injectors utilizing cartridges for the administration of injectionable compounds, it is desired to provide a

lyophilized compound in an improved cartridge suitable for use in an injector pen.

The present invention, in one form thereof, provides a method of lyophilizing a compound in a glass cartridge and sealing the same utilizing a closure cap with a seal, and encapsulating the same into a cartridge assembly.

A method of lyophilizing and sealing an injectionable product within a cartridge is provided which includes, providing a cartridge having a neck defining a first opening therein, and a second opening therein distal the first opening, the neck including a circumferential radially outwardly extending flange adjacent the first opening, inserting a plunger in the second opening, and inserting the product to be lyophilized into the cartridge. Further, there is provided a cap having a cylindrical portion and a seal, the cylindrical portion including an open bottom receivable over the neck, the cap including a top having an opening therein for receipt of a needle therethrough, at least one vent circumferentially disposed in the cap, and a deformable ledge in the cap extending radially inwardly from the cylindrical portion axially below the vent, the seal being axially disposed between the vent and the top so as to block the top opening. The cap is then placed onto the neck such that the deformable ledge rests upon the neck flange and the vent is in communication with the neck opening, after which the cartridge with the cap is placed in a lyophilizing chamber, wherein the product is lyophilized, and the cap is closed by exerting a downward pressure upon the cap such that the deformable ledge yieldably snaps around the neck flange to be lockingly retained thereunder, the vent is closed from communication with the neck opening, and the seal is compressed into sealing engagement with the neck opening by downward pressure exerted by the top thereby providing an air impermeable barrier between the top opening and the neck opening.

The method of sealing a lyophilized product within a cartridge is further characterized by providing a sleeve having a first open end and a radially inwardly extending circumferential ledge into which the cartridge is placed. The cartridge is axially seated against the ledge and the sleeve is permanently attached to the cap.

A plunger rod tip having a plunger head is received in the sleeve between the plunger and ledge such that the plunger head is axially adjacent the plunger.

The present invention, in one form thereof, provides a cartridge assembly containing a lyophilized drug having a cartridge, a cap and seal, a cartridge sleeve, and a plunger mechanism forming a disposable portion of an injector pen.

A cartridge assembly for holding a lyophilized drug and forming a disposable part of an injection pen comprises a cartridge having a plug in one end and a neck on another end, the cartridge including a circumferentially extending flange about the neck, the neck defining an opening therein, a cap disposed about the neck, the cap having a first cylindrical portion including an open bottom received over the neck, a top having an opening therein for receipt of a needle therethrough, and a deformable ledge extending radially inwardly from the first cylindrical portion and lockingly retained under the neck flange. A resilient seal is disposed in the cap between the neck opening and the top opening forming an impermeable barrier therebetween, with a sleeve radially disposed about and permanently attached to the cartridge.

Further, the sleeve is permanently attached to the cap, and includes a first cylindrical portion adapted to receive the cartridge and a second cylindrical portion axially below the first cylindrical portion and concentric therewith, and a radially inward circumferentially extending ledge defined at the junction of the first and second cylinder for axially retaining the one end of the cartridge.

In one form thereof the present invention provides a method and apparatus for reconstituting a lyophilized compound, the lyophilized compound contained within an interior space defined by an inner wall of the cartridge having an inlet at one end thereof. The method comprising the step of injecting a diluent into the cartridge via the inlet such that the diluent impinges on and runs down the inner wall of the cartridge to thereby contact the compound, whereby foaming of the compound is alleviated.

A connector is releasably secured to the inlet end of the cartridge and adapted to receive and hold a syringe containing a diluent. The connector has a first portion defining a longitudinal axis which forms an oblique angle with the longitudinal axis of the cartridge. The syringe is supported by the connector at the oblique angle whereby the diluent is injected into the cartridge via the inlet at the oblique angle so that the diluent impinges on the wall of the cartridge.

The cartridge of the present invention is adapted to be used with an injector pen apparatus for administering a drug. The apparatus comprises a cartridge assembly having a cartridge with a movable plunger therein and an inlet on one end thereof. The cartridge assembly includes a rod tip having a recess therein and disposed axially adjacent the plunger and is adapted to exert pressure upon the plunger for dispensing the drug from the cartridge. An injector pen is releasably engaged with the cartridge assembly, the pen including a movable rod adapted to engage the recess of the rod tip in order to move the rod tip during dispensing of the drug. For injection of the drug, the rod retracts a known distance away from the plunger within the recess of the rod tip. The rod is then advanced towards the plunger a selected number of discrete increments as determined by the number of clicks depending on the desired dosage to be administered. During injection, the rod then advances the known distance towards the plunger which causes the plunger to advance

the distance determined by the amount of discrete increments. The rod then retracts the known distance within the travel length of the rod tip.

It is an advantage of the present invention that the closure cap does not require close tolerances in cartridge manufacture.

It is another advantage of the present invention in that the cartridge, closure cap with seal, and cartridge case with plunger form a tamper resistant package.

It is yet another advantage of the present invention that the cartridge assembly prevents the plunger from outwardly moving during shipment of the cartridge assembly and during reconstitution of the lyophilized drug contained therein.

It is further an advantage of the present invention that foaming of the lyophilized compound is prevented during reconstitution thereof.

It is still another advantage of the present invention in that the cartridge assembly is protected from breakage.

It is also an advantage of the present invention that container integrity for the drug is increased.

The above mentioned and other features and objects of this invention, and the manner of attaining them, will become more apparent and the invention itself will be better understood by reference to the following description of embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

Fig. 1A is a perspective view of the closure cap according to an aspect of the present invention;

Fig. 1B is a bottom view of the closure cap taken along line 1B-1B of Fig. 2;

Fig. 2 is a sectional elevational view of the closure cap taken along line 2-2 of Fig. 1A;

Fig. 3 is an elevational cutaway view of the glass cartridge and plunger;

Fig. 4 is an elevational cutaway view of the glass cartridge with plunger seated on a shelf with the closure cap in an open condition;

Fig. 5 is an elevational cutaway view of the glass cartridge with plunger seated on a shelf with the closure cap in a closed position;

Fig. 6 is an elevational cutaway view of a cartridge assembly with user needle and cap;

Fig. 7 is an elevational cutaway view of the cartridge assembly according to an embodiment of the present invention;

Fig. 8 is a partial cutaway view of the cartridge assembly according to an embodiment of the present invention installed on a dispensing pen unit;

Fig. 9 is an elevational cutaway view of the cartridge assembly during reconstitution;

Fig. 10 is an elevational cutaway view of the cartridge assembly with connector and connector lid before insertion into a dispensing pen and reconstitution;

Fig. 11 is a partial cutaway view of the cartridge assembly installed on a dispensing pen; and

Figs. 12-14 are partial cutaway views of the plunger and rod mechanism as utilized with the dispensing pen illustrating the injection process.

Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate a preferred embodiment of the invention, in one form thereof, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

Referring now to Figs. 1A, 1B, and 2, there is shown a closure or lyophilization cap 20 in accordance with an aspect of the present invention. In general, cap 20 is preferably made of an injection molded plastic, although other suitable materials as known in the art may be utilized with the cap thus fabricated accordingly. Cap 20 has a cylindrical bottom portion or skirt 22 of a given

axial length and inner radius sufficient to extend about at least a portion of a lyophilization cartridge. As further described hereinbelow, bottom portion or skirt 22 stabilizes cap 20 when placed onto cartridge 58 in the open position during lyophilization, and serves as a guide during closing of the cap. Cylindrical bottom portion 22 has a slightly upwardly and inwardly sloping annular shoulder 24, with a cylindrical top portion or neck 26 disposed axially above and inwardly concentric to cylindrical bottom portion 22. Top portion 26 includes threads 28 circumferentially formed on the outer upper periphery thereof which are adapted to threadedly receive a connector 30 (Figs. 9 and 10) and needle assembly 32 (Fig. 6) both of which are described in more detail hereinbelow. Formed in cylindrical top portion 26 below threads 28 are two diametrically opposed circumferentially extending rectangular openings 34 and 36 which serve to vent moisture from cartridge 58 (Figs. 3-5) during lyophilization and which allow the oxygen purge and nitrogen overlay process to occur thereafter.

As best seen in Fig. 1B, extending radially inward from wall 33 and 35 just below openings 34 and 36 are two ledges 38 and 40 having a circumferential length roughly corresponding to openings 34 and 36. As will be described in more detail hereinbelow, ledges 34 and 36 serve the dual function of allowing closure cap 20 to be seated upon cartridge 58 thus permitting communication between openings 34, 36 and the interior 60 of cartridge 58, and of snapping around and under circumferential flange 62 of cartridge neck 64 upon closing cap 20. Ledges 38 and 40 are sized and shaped so as to reduce the closing pressure required during the closing process, described hereinbelow, and to minimize the amount of cap deformation as closure is taking place. Cap 20 includes a top 41 which downwardly slopes from the outer upper edge of cylindrical top portion 26 terminating at an aperture 46 adapted to expose a seal 52 and receive a needle as

described in detail hereinbelow. Two arched slots 42 and 44 are disposed in top portion 41 each axially upwardly of a respective side opening 34, 36. Arched slots 42 and 44 are formed during the molding process in order to achieve the undercut ledges 38 and 40 sufficiently large enough to allow for variations in the diameters of cartridge flanges.

Defined at the level 50 of ledges 38, 40 interior to cap 20 are walls 33, 35, 47, and 48 that define an oval or elliptic surface 49 whose major axis is transverse to an axis defined by connecting the middle of side openings 34, 36 or ledges 38, 40 such that each longitudinal end of oval or ellipse 49 is located 90° from each ledge 38 and 40. Walls 47 and 48 are thinner than walls 33 and 35 carrying ledge 38 and 40 so that as the ledges are forced outwardly during seating of cap 20, walls 47, 48 can move inward to accommodate such outward movement of walls 33 and 35 carrying ledges 38, 40. However, the thicker walls 33, 35 provide adequate support for ledges 38, 40 to prevent dislodgement of cap 20 from cartridge 58. This reduces the pressure required to close cap 20 onto cartridge 58 after lyophilization and nitrogen purge in order to prevent stress fractures in cap 20 and allow for more cartridges to be closed at one time. Such elliptical configuration of walls 33, 35, 47 and 48 extends the entire inner axial length thereof.

A circumferential ridge 51 is disposed about the interior of cylindrical top portion 26 axially below and adjacent top 41. Ridge 51 permits seal 52, such as for instance a laminated, two-piece rubber seal, to be seated therein without dislodging for efficient covering of opening 46.

The structure of cap 20 assists the natural deformation that occurs during the closure process. Thus, as cap 20 is pressed onto cartridge 58, ledges 38, 40 spring outward to allow it to go over and then underneath neck flange 62 (see Fig. 3).

What has thus been described hereinabove is a cap adapted to be seated upon a cartridge during lyophilization and which effectively and positively closes upon the cartridge to securely hold a disc seal about the opening. The cap is designed for efficient lyophilization and optimal nitrogen sealability while requiring only a minimum amount of closure force.

The process of lyophilizing a compound in cartridge 58 utilizing the hereinabove described cap 20 will now be described in conjunction with Figs. 3-5. First, it should be noted that the various parts are sterilized prior to placement in the freeze dryer so that the compound to be lyophilized will be free from contamination. Secondly, it should be noted that a plurality of cartridges (up to 6000 or more) are generally lyophilized at one time. The cartridges are held in blocks defining a matrix of rows and columns of cartridges with the blocks placed in a freeze dryer chamber between movable shelve units, described hereinbelow. A typical configuration is 2000 per layer with three layers. The general structure of the various elements will also be described when introduced during the description of the process.

Cartridge 58 is manufactured of glass and consists of a tube portion 59 defining an inner chamber 60 and which openly terminates at one end with a circumferential inwardly bulbous lip 56. The other end of tube 59 includes an upwardly and inwardly sloping shoulder portion 66, a reduced diameter neck 64 and a rim 63 having circumferential flange 62 having a circumferential radius greater than that of neck 64. The end of cartridge 58 including flange 62 defines an opening 68 which communicates with inner chamber 60. Recessed neck 64 has a diameter that is smaller than shoulder 66. A rubber plunger 54 having knobs 55 is first disposed in the end having lip 56 just far enough into cartridge 58 such that the end of plunger 54 is adjacent lip 56. This is to keep the inside of cartridge 58 sterile after lyophilization.

Cartridge 58 with plunger 54 is placed between shelves 72 and 74 in the freeze dryer (not shown) with the liquid compound or drug 70 to be lyophilized contained therein. Cap 20 having rubber disc seal 52 disposed therein is placed over flange 62 defining a first or open position, the placement of cap 20 onto cartridge 58 occurring either before placement of cartridge 58 into the freeze dryer or thereafter. However, compound 70 is placed into cartridge 58 before the placement of cap 20 upon flange 62. Seal 52 is preferably a laminate of two different materials, the upper material 52a being a good sealing material, with the bottom material 52b being a good product contact material such as, for example, a normal butyl rubber compound. However, any resilient sealing material may be utilized which provides a good product contact material on the bottom and a good sealing material on the top.

Referring specifically to Fig. 4, cap 20 is designed such that ledges 38 and 40 rest on top of flange 62. In the first or open position a part of cylindrical bottom portion 22 circumferentially surrounds an upper part of tube 59 thereby serving as a stabilizer for cap 20 and a guide when cap 20 is moved to the second or closed position. Seal 52 is held in an elevated position above cartridge opening 68, while side openings 34 and 36 are above opening 68 thus allowing communication between the ambient atmosphere and inner chamber 60 of cartridge 58. At this point lyophilization begins.

Lyophilization, or freeze drying, which is represented in Fig. 4 as an upward and outward arrow, purges the moisture from compound 70 such that a waterless compound is left. Although the arrow is shown exiting only one side opening 36, it should be understood that the moisture is vented out through both openings 34, 36 during lyophilization. Once the moisture has been vented out of cartridge 58, oxygen is purged from the lyophilization chamber and thus cartridge 58. A nitrogen overlay process

is then initiated. The nitrogen overlay process is represented in Fig. 4 as an inward and downward arrow entering from side opening 34, but as is the case for the venting of moisture and oxygen purge, the nitrogen enters through both side openings 34 and 36 to fill the entire inner space 60 of cartridge 58 not occupied by the now lyophilized compound 70. The nitrogen overlay process is used where the lyophilized compound is oxygen sensitive, as, for example, HGH.

At this point and referring now to Fig. 5, shelves 72 and 74 move vertically together in order to close cap 20 onto neck 64. As described above, cap 20 includes an oval or elliptical indentation 47 and inner wall 48 which allows cap 20 and ledges 38 and 40 to deform and flex so that ledges 38 and 40 snap around flange 62 as cap 20 is downwardly pressed by the pressure exerted by closing shelves 72 and 74. A force of only about 10-12 lbs. is thus necessary to effect closure of cap 20 about neck 64 and neck flange 62. Once in place, cylindrical bottom portion 22 extends about an upper part of tube 59, while ledges 38 and 40 prohibits removal of cap 20 by extending under neck flange 62 between the flange and sloped shoulder section 66.

Upon closure of cap 20, seal 52 is compressed between the top of rim and downwardly sloped cap top 41 to effect a positive, airtight seal between the ambient atmosphere and the nitrogen and lyophilized compound within cartridge 58. There is no need for a crimp seal, while both the lyophilization and closure processes are completed within the lyophilizing chamber. At this point, the sealed cartridge may be removed from the lyophilizing chamber. A cake or plug of compound 70 is thus sealed within a nitrogen filled cartridge.

After lyophilization, and referring to Fig. 7, sealed cartridge 58 is then placed into a cartridge sleeve, barrel, or retainer 76 through an opening 77 in one end thereof. The sleeve is preferably made from a suitable

plastic or other material which provides protection for the glass cartridge.

Sleeve 76 comprises a first tubular portion 78 having an inner diameter 79 of sufficient size such that a segment of first tubular portion 78 radially surrounds or overlaps cylindrical bottom portion 22 of cap 20. At this junction, sleeve 76 is attached or sealed to cap 20 by use of a solvent, adhesive bond, snap fit, sonic weld, or the like, such that cartridge 58 is retainingly held in sleeve 76. Sleeve 76 also includes a second tubular portion 80 having a smaller diameter than first tubular portion 78 such that tube 59 of cartridge 58 is inwardly circumjacent the inner diameter thereof. Threads 86 on the outer periphery of second tubular portion 80 permit sleeve 76 to be received onto an injection pen device.

Sleeve 76 further comprises a third tubular portion 82 having a smaller diameter than second tubular portion 80, the second tubular portion defining an annular stop or ledge 84 at the junction of second and third tubular portions 80 and 82. Stop 84 supports lip 56 such that tube 59 is supported thereon. A sleeve cap 88 optionally may fit about the top of the cartridge assembly 90 to further protect the seal assembly. Thus, the cartridge is securely held by and contained within sleeve 76 and ready for reconstitution before administration and placement into an injector pen dispenser.

Sleeve 76 has a smaller diameter opening 69 at the other end through which extends a plunger rod tip 71. Rod tip 71 is placed within sleeve 76 before insertion of cartridge 58, and has a circular rod head 73, slightly less than the inner diameter of cartridge 58, on one end of a hollow cylindrical body 85. The lower portion of rod head 73 is seated against sleeve ledge 84 and is of sufficient diameter such that rod tip 71 is retained in sleeve 76. Rod tip body 85 is of sufficient length to axially extend from head 73 to the axial end of third tubular portion 82. Cylindrical body 85 defines an

axially elongated cylindrical recess or bore 107. Recess 107 defined by cylindrical body 85 between bottom portion 81 of rod head 73 and end portion 83 is of a specific axial length, for example, eight and nine tenths millimeters (8.9 mm). The upper surface of circular rod head 73 of rod tip 71 abuts plunger 54 and includes an annular groove 75 into which knobs 55 of plunger 54 are seated. As pressure is applied to plunger 54 in order to administer the reconstituted compound, plunger 54, being an elastomeric or rubber, has a tendency to deform during compression. However, because of its resiliency, plunger 54 returns to its original shape, which sequence could cause weeping of the liquid from around the plunger. Rod head 73 serves to distribute the load exerted by the compression of rod tip 71 in order to eliminate weeping from about plunger 54 which could occur as a result of uneven or localized compression of plunger 54. Annular groove 75 retains knobs 55 to prevent lateral deformation, which could cause weeping.

As shown in Fig. 10, a connector 30 is threadedly attached to threads 28 of cap 20. This occurs after placement of cartridge 58 in sleeve 76 and attachment of cap 20 thereto. Connector 30, introduced hereinabove, is threadedly attached to threads 28 of cap 20 and includes an angled first section 92 and a larger diameter second section 94. First section 92 is tubular in shape and includes an upper section 111 and, at its lower end, an angled neck portion 113 having mating threads for threads 28. Neck portion 113 is essentially concentric and defines a common axis with cartridge 58. Upper section 111 defines an axis which thus forms an oblique angle with the axis of neck portion 113. Larger diameter portion 94 is eccentric with upper section 111 of first section 92. A common axis is also defined between upper section 111 and portion 94.

A lid 95 is snapped in place over cylindrical second section 94 thereby sealing the space there between. This

entire assembly is then sterilized so that the contents of the cartridge and the area about the disc seal is sterile for later reconstitution and administration.

Reconstitution is performed as shown in Fig. 9. After removal of connector lid 95, connector 30 is thus adapted to receive a syringe 96 in second section 94 which supports syringe 96 but allows needle 98 to enter hole 46 and penetrate seal 52 such that only a small section of needle 98 extends into cartridge 58. During reconstitution, the action produced by the force of moving diluent upon the lyophilized cake (e.g. HGH) triggers a reaction which causes the HGH cake to become agitated and foam. Foaming undesirably creates air bubbles, thereby limiting the amount of diluent that can be added to the cartridge. This can result in improper dilution ratios of the lyophilized compound. Furthermore, once the foam subsides, too large a headspace is created within the cartridge.

According to one aspect of the present invention, connector 30 is obliquely angled as described above such that needle 98 is oriented toward and preferably in close proximity to wall 58 and injects diluent 102 down the side of the interior wall of cartridge 58 in order to prevent foaming of the compound during the reconstitution process. Side impingement of the diluent reduces the velocity of the diluent as it travels toward and onto the HGH cake. This indirect administration of the diluent by causing the diluent to impinge on the inner side wall of cartridge 58 and then run down around and into the HGH prevents foaming.

Syringe 96 is prefilled with a suitable diluent 102, and as plunger 100 of syringe 96 forces fluid into the lyophilized cartridge, the nitrogen in cartridge 58 is compressed. Releasing syringe plunger rod 100 while holding the syringe above the cartridge, allows the pressure in the cartridge to equilibrate by venting the nitrogen into the syringe, leaving the diluent in the

cartridge to mix with the lyophilized drug. The syringe is then removed and discarded.

A transfer needle 32, such as those manufactured by Becton-Dickinson, can then be threadedly attached to cap 20 where connector 30 was attached during reconstitution. This is shown in Fig. 6. The typical transfer needle 32 is a double-ended needle 110, which extends in one direction through hole 46 in top 41 and seal 52 to communicate with the reconstituted drug within the cartridge. Needle 110 is secured in a needle housing 112 and protected during nonuse by a plastic cap 114 and needle assembly protector cap 116.

Referring in particular now to Fig. 8, cartridge assembly 90 is threadedly attached to an injector pen 104, such as that manufactured by Disetronic AB of Burgdorf, Switzerland. A plunger rod 108 fits into recess 107 of rod tip 71 in order to effect ejection of the reconstituted drug from the cartridge. The inside length of rod tip 71 is adapted to retain the injector pen plunger rod 108 during the injector pen's compression and retraction stroke. When the drug is to be administered to the patient, the needle assembly 32 as shown in Fig. 6 is attached to cap 20 as described hereinabove.

One such type of injector pen is shown in Fig. 11 and its operation described in conjunction with additional Figs. 12-14. Referring to Fig. 11, cartridge assembly 90 is shown connected to injector pen 104 via complementary threads 86, 101. Injector pen 104 includes a pen rod 108, a dose knob 118 and a release button 120. Pen rod 108 fits into a suitable mechanism within pen body 106 for providing the injector function as described below in conjunction with Figs. 12-14.

It should be noted with respect to Figs. 12-14 that for simplicity of discussion and understanding of an aspect of the present invention that only rubber plunger 54 and plunger rod tip 71 of the cartridge assembly are shown in relationship to pen 104 and, in particular pen

rod 108. To load the assembly for the first time, release button 120 is pushed such that dose knob 118 pops out. At this point, pen rod 108 retracts a known, or predetermined distance, for example 8.1 millimeters away from plunger 54 within recess 107. Dose knob 118 is then turned until dose knob 118 stops which causes pen rod 108 to travel forward towards plunger 54 a set maximum amount for purging. Upon retraction, pen rod 108 cooperates with rod tip 71 in that pen rod 108 does not travel any more than 8.1 millimeters out of the 8.9 mm (for example) recess 107 of the rod tip 71. End 109 of plunger rod 108 thus never retracts past a plane defined at the end 83 of rod tip 71 perpendicular to an axis of elongation of rod tip 71. Thus, rod 108 never disengages from recess 107.

The rod tip, being an integral part of the housing for the cartridge assembly prevents the plunger 54 in the cartridge from being forced out during the reconstitution process. Further, rod tip 71 allows movement required by the pen's plunger rod 108 during dose setting and injection. When dose knob 118 is pushed in, the unit purges 95 percent of all of the air in the cartridge in order to obtain a proper head space. Thus, after reconstitution, and initial purging, the injector pen assembly is ready for the administration process as shown in Fig. 11.

In order to administer the drug to the patient, release button 120 is pressed which causes dose knob 118 to pop out and correspondingly cause pen rod 108 to retract the 8.1 mm maximum travel distance within the 8.9 mm rod tip 71, each action being depicted by respective arrows in Fig. 12. As noted hereinabove, end 109 never retracts past end 83. Dose knob 118 is then turned through so many clicks, the clicks corresponding to volume units of dosage depending on the required amount of dosage. Each click corresponding to a given volume of injectionable liquid. This is depicted in Fig. 13. As the required number of clicks are set via dose knob 118,

pen rod 108 correspondingly moves forward an amount equal to the number of clicks, with each click correspondingly moving pen rod 108 a predetermined distance being coordinated with a set dosage amount.

As shown in Fig. 14, when dose knob 118 is depressed, pen rod 108 thus contacts rod head 73 of rod tip 71 to administer the drug by traveling the 8.1 mm distance. Upon retraction of pen rod 108 in order to administer another dose, pen rod 108 retracts the set 8.1 mm distance within the 8.9 mm recess 107. This ensures that pen rod 108 never comes out of rod tip 107.

The process as depicted in Figs. 12-14 is repeated at the prescribed times until all of the drug has been administered. A dose indication device 122 is provided to visually indicate the dosage set by dose knob 118. Such dose indication may be purely mechanical in nature or electronic, such as an LCD display.

Once the entire drug has been administered to the patient, the entire cartridge assembly and patient needle assembly is then discarded. The injector pen is then ready for another cartridge assembly 90.

While this invention has been described as having a preferred design, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains and which fall within the limits of the appended claims.

CLAIMS

1. A method of lyophilizing and sealing an injectionable product within a cartridge, the method comprising the steps of: providing an elongate cartridge (58) having on a first end thereof a shoulder (66), a rim (63) defining a first opening and having a circumferential radially outwardly extending flange (62) adjacent said first opening, and a neck (64) disposed axially between said flange and shoulder, said neck having a diameter smaller than said flange and shoulder, said cartridge including a second opening on a second end thereof distal said first opening; and inserting a plunger (54) in said second opening; characterized by:

providing a cap (20) having a cylindrical portion and a seal (52), said cylindrical portion including an open bottom receivable over said neck, said cap including a top having an opening therein for receipt of a needle therethrough, at least one vent (34) circumferentially disposed in said cap, and at least two deformable ledges (38,40) on said cap extending radially inwardly from said cylindrical portion axially below said vent, said seal being axially disposed between said vent and said top so as to block said top opening;

inserting the product to be lyophilized into said cartridge (58);

placing said cap onto said cartridge such that said deformable ledges (38,40) rest upon said flange (62) and said vent is in fluid communication with said cartridge first opening; placing said cartridge with said cap in a lyophilizing chamber; lyophilizing the product; and

closing said cap by exerting a downward pressure upon said cap such that said deformable ledges yieldably snap around said flange (62) and into said neck to be lockingly retained therein, said vent (34) is blocked from communication with said cartridge first opening, and said seal (52) is pressed into sealing engagement with said rim (63) by downward pressure exerted by said top thereby

providing an air impermeable barrier between said top opening and said cartridge first opening.

2. The method of claim 1, characterized in that the step of closing said cap (20) is preceded by the steps of purging oxygen from said cartridge (58) and providing a nitrogen overlay in said cartridge.

3. The method of claim 1, further characterized by: providing a sleeve (78) having a first open end for receiving said cartridge (58) and a radially inwardly extending stop (84); and placing said cartridge into said first open end of said sleeve such that said cartridge is positively axially retained in said sleeve against said stop.

4. The method of claim 3, characterized by the subsequent step of permanently attaching said sleeve (78) to said cap (20).

5. The method of claim 3, characterized in that said sleeve (78) includes a second open end distal said first open end and axially below said sleeve stop, and the step of placing said cartridge into said sleeve is preceded by the step of inserting a plunger rod tip (71) having a head (73) in said sleeve such that said plunger rod tip extends from said second opening and said head is axially adjacent said plunger (54).

6. The method of claim 5, further characterized by the step of capturing said head (73) between said sleeve ledge (84) and said plunger (54).

7. The method of claim 1, characterized in that the step of placing the cartridge (58) in a lyophilizing chamber includes supporting said cartridge on a first surface (74), and the step of closing said cap includes exerting a downward pressure upon said cap (20) by contact of a second surface (72) upon said cap induced by relative vertical movement between said first and second surfaces.

8. A cartridge assembly for holding a lyophilized drug and forming a disposable part of an injection pen, the cartridge assembly comprising:

an elongate cartridge (58) having on a first end thereof a shoulder (66), and a rim (63) defining a first opening and having a circumferential radially outwardly extending flange (62) adjacent said first opening and a neck (64) disposed axially between said flange and shoulder, said neck having a diameter smaller than said flange and shoulder, said cartridge including a second opening on a second end thereof distal said first opening;

a cap (20) disposed on said first end of said cartridge, said cap having a first cylindrical portion including an open bottom received over said first end, a top having an opening therein for receipt of a needle therethrough, and at least two elastically deformable ledges (38,40) extending radially inwardly from said first cylindrical portion and lockingly retained under said neck flange;

a resilient seal (52) in said cap disposed between said first opening and said top opening and forming an impermeable barrier therebetween a vent opening in said cap below said seal; a sleeve (78) radially disposed about and permanently attached to said cap; and

a plunger rod tip (71) slidably disposed in said sleeve, said plunger rod tip including a head (73) axially adjacent said plunger for exerting pressure against said plunger during administration of the drug.

9. The cartridge assembly of claim 8, characterized in that said sleeve (78) includes a first cylindrical portion adapted to receive said cartridge and a second cylindrical portion axially below said first cylindrical portion and concentric therewith, and a radially inward circumferentially extending ledge (84) defined at the junction of said first and second cylinder for axially retaining said one end of said cartridge.

10. The cartridge assembly of claim 8, characterized in that said rim (63) of said cartridge outwardly tapers for compressingly sealing said resilient seal (52) between said cartridge and said cap.

11. The cartridge assembly of claim 8, characterized in that said cap (20) includes an oval shaped wall carrying said ledges (38,40) wherein said wall is thinner along the major axis of the oval than along the minor axis of the oval, and said ledges are disposed generally on the minor axis of the oval.

12. The cap and cartridge assembly of claim 8, characterized in that said deformable ledge comprises two circumferential and inwardly extending ledges (38,40) separated by two arcuate portions of an oval-shaped wall (50) and said ledges are located on the minor axis of said oval-shaped wall.

13. The cap and cartridge assembly of claim 12, characterized in that said oval-shaped wall (50) is thinner along the major axis of the oval than along the minor axis of the oval.

14. A method reconstituting a lyophilized compound, the lyophilized compound contained within an interior space defined by an inner wall of a cartridge (59) having an inlet at one end thereof, the method comprising the steps of: attaching a connector (30) to the inlet end of the cartridge, the connector having an interior space and defining an axis along a longitudinal length thereof, the axis of the connector forming an oblique angle relative to the axis of the cartridge; placing a syringe (96) having a needle (98) and containing the diluent into the interior space of the connector, such that the needle (98) is oriented obliquely toward the inner wall of the cartridge; and injecting a diluent from the syringe into the cartridge via the inlet such that the diluent impinges on and runs down the inner wall of the cartridge before contacting the compound (70) whereby foaming of the compound is prevented.

15. An apparatus for reconstituting a lyophilized drug contained within an inner space of a cartridge, the cartridge (59) having an inlet on one end thereof, and defining a longitudinal axis extending through the inlet,

the apparatus comprising: a connector (30) releasably secured to the inlet end of the cartridge and adapted to receive and hold a syringe (96) containing a diluent, the connector having a first portion (111) defining a longitudinal axis which forms an oblique angle with the longitudinal axis of the cartridge, the syringe being supported by the connector at the oblique angle whereby the diluent is injected into the cartridge via the inlet at the oblique angle.

16. The apparatus of claim 15, characterized in that said connector (30) is received on the inlet end of the cartridge, the connector further including a second portion (113) eccentric with said first portion, said second portion having a larger diameter than a diameter of said first portion and adapted to retain and support the syringe.

17. An injector pen and cartridge apparatus for administering a drug, the apparatus comprising: a cartridge assembly (90) having a cartridge with a movable plunger (54) therein and an inlet on one end thereof, said cartridge assembly including a rod tip (71) disposed axially adjacent said plunger and adapted to exert pressure upon said plunger for dispensing the drug from said cartridge, said rod tip including a recess (107) of a given axial length therein; and an injector pen releasably engaged with said cartridge assembly, said pen including a movable rod (108) received in said recess (107) and engaging said rod tip in order to advance said rod tip during dispensing of the drug; characterized in that said movable rod (108) has a retraction travel length that is less than the axial length of said recess whereby said movable rod remains engaged with said rod tip.

18. The cartridge assembly of Claim 17 characterized in that said plunger rod tip (73) is captured by said ledge (84) of said sleeve to thereby retain said plunger rod tip in said sleeve.

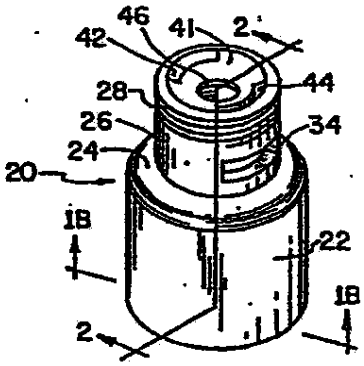


FIG. 1A

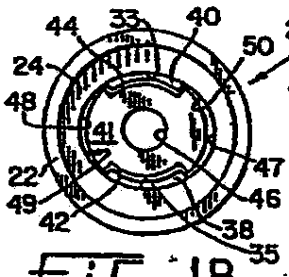


FIG. 1B

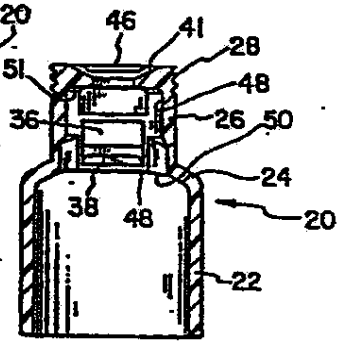


FIG. 2

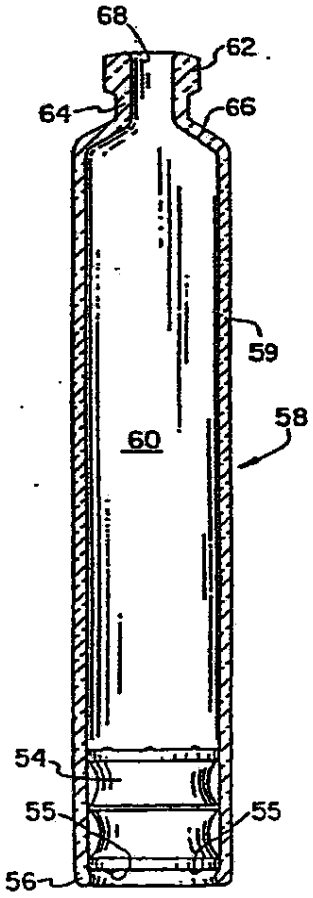


FIG. 3

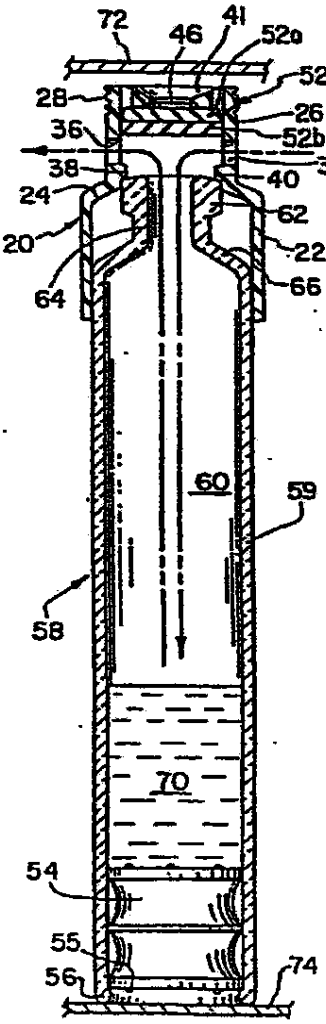
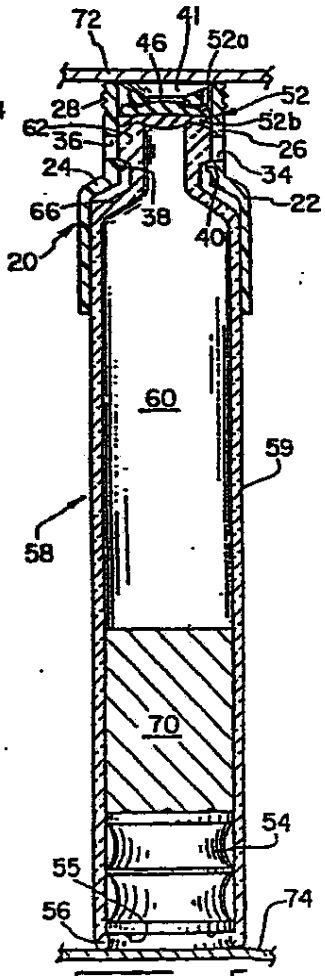


FIG. 4



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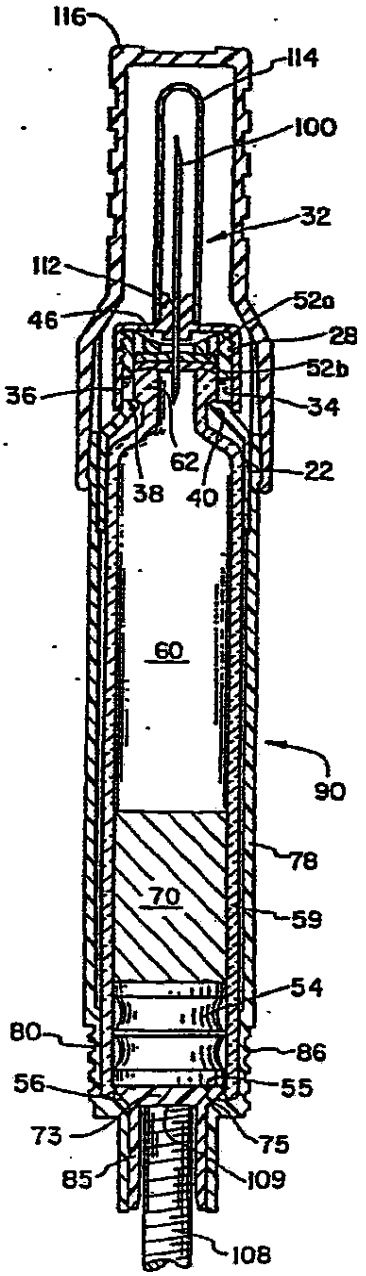
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52b
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FIG. 6

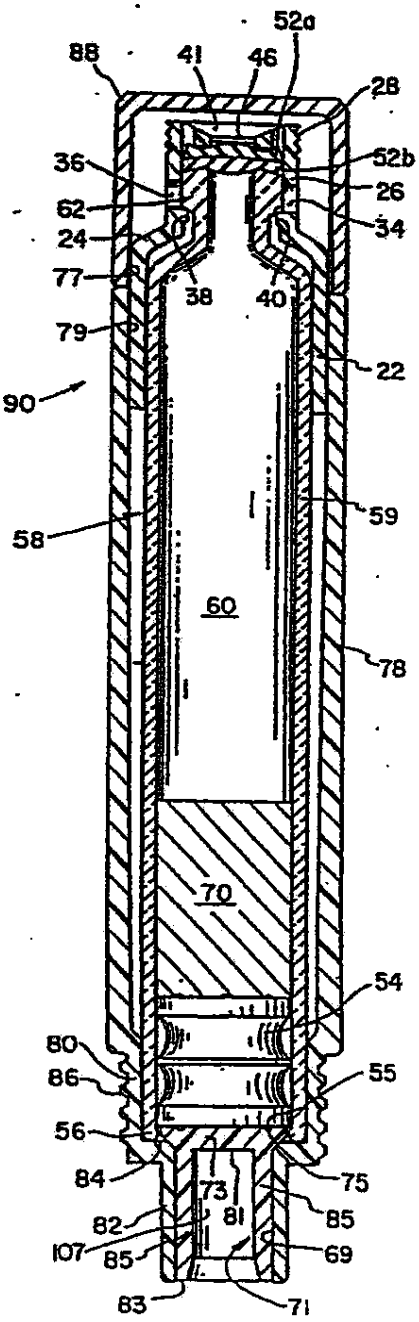
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FIG. 7

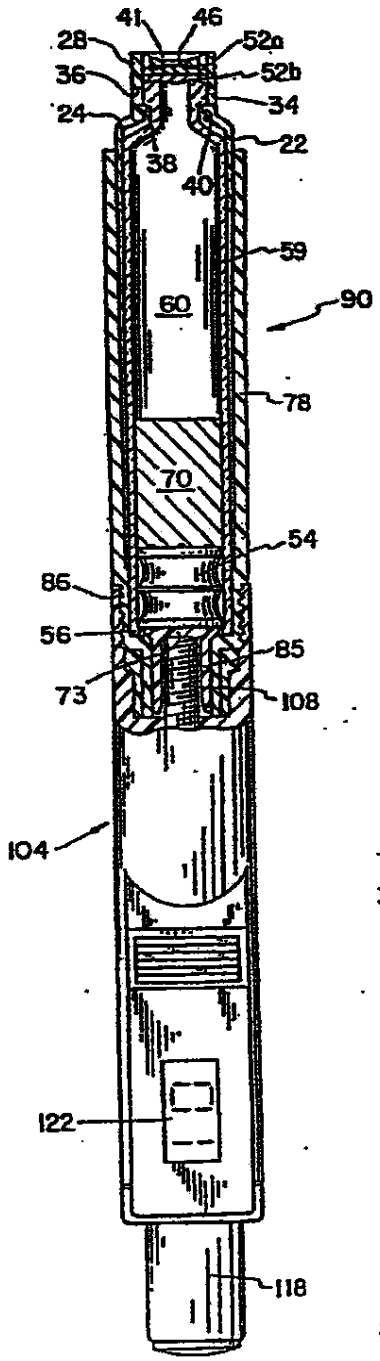
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FIG. 8

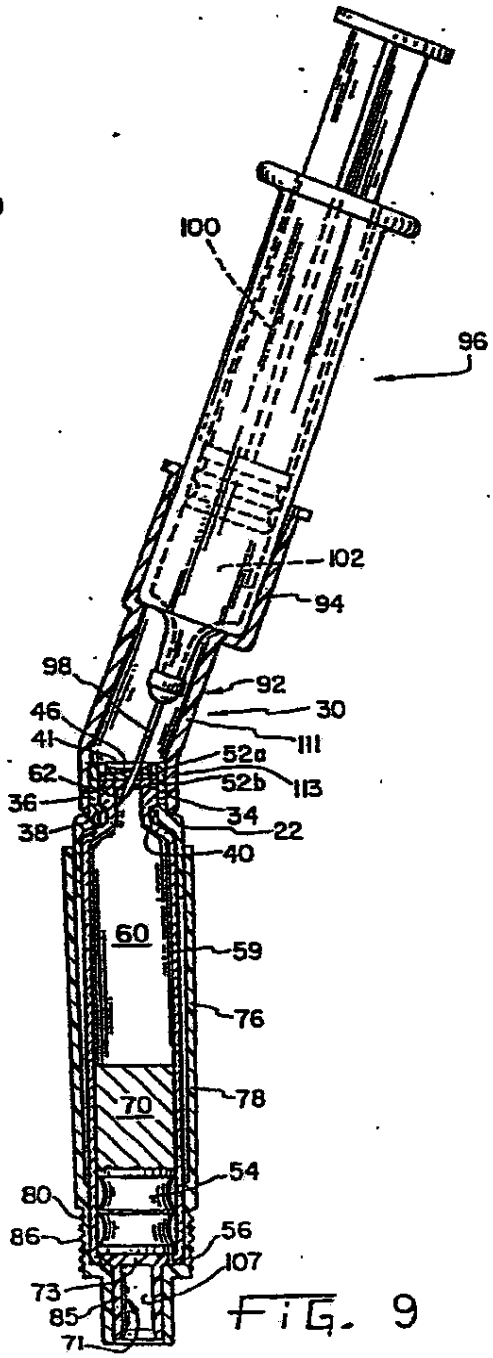
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FIG. 9

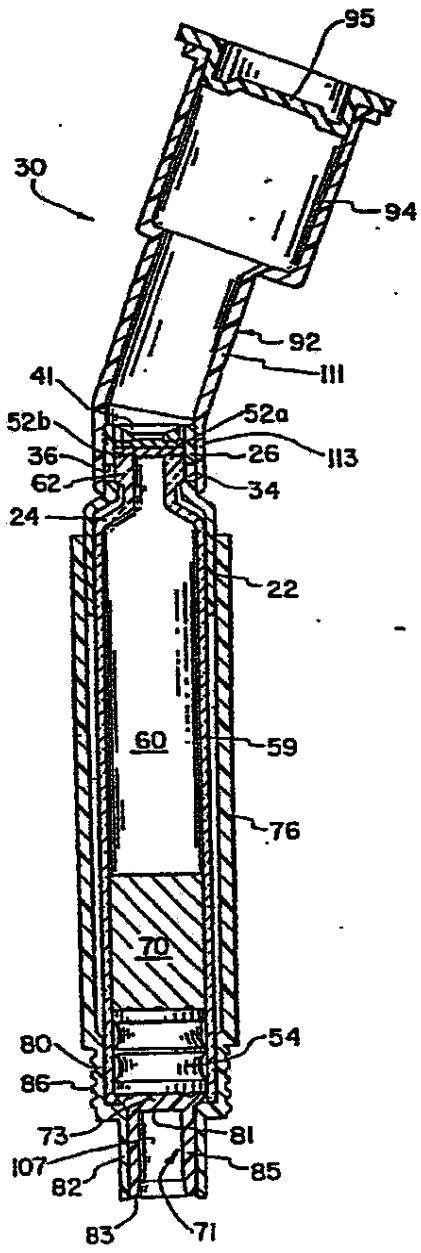
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FIG. 10

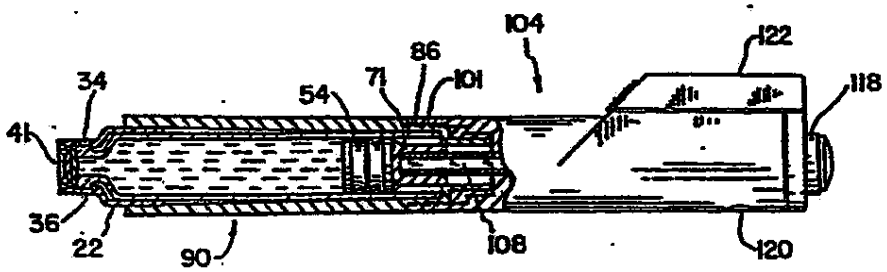

FIG. 11

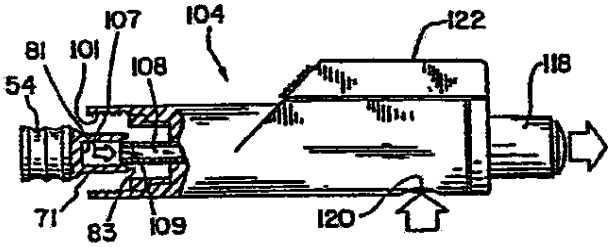

FIG. 12

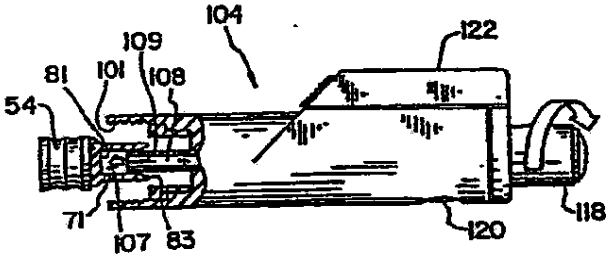

FIG. 13

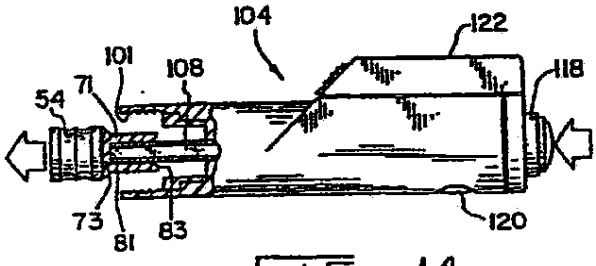

FIG. 14

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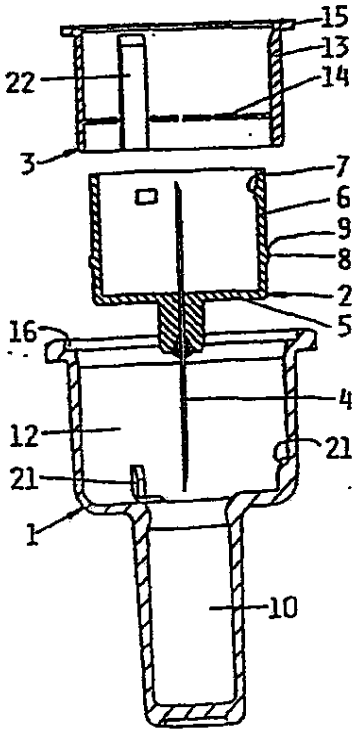
Published
With international search report.

(54) Title: NEEDLE MAGAZINE

(57) Abstract

A magazine for storing and final disposal of a snap-on needle unit (2) has a compartment (1) having a bottom, a cylindric side wall, and an access opening, which compartment accomodates the needle unit with a gap between the outer side wall of this needle unit and the inner side wall of the compartment. A circle of tongue shaped protrusions (14) are at one end thereof hinged at the inner surface of the side wall of the compartment and are at their other end free. The length of the protrusions exceeds the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.



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NEEDLE MAGAZINE

The invention relates to a magazine for storing and final disposal of a snap-on needle unit carrying a needle mounted in a hub comprising a sleeve with an open end for insertion of a needle receiving part of a syringe and exhibiting a cylindric outer wall.

A snap-on needle unit is a unit which may be mounted on a syringe by an axial movement of the syringe and the needle unit towards each other. During this movement a needle receiving part of the syringe is passed into a sleeve of a needle hub forming part of the needle unit until protrusions on the inner surface of the sleeve engage recesses in the needle receiving part.

In opposition to needle units which a screwed onto the syringe an axial pressure must be exerted on the needle unit and the syringe to provide the snap engagement between the two parts. Correspondingly a certain axial force must be used to pull the syringe and the needle unit apart again when after use the needle is removed from the syringe for final disposal.

During mounting and dismounting of the needle unit it is important that the outer pointed end of the needle is protected so that neither the user nor an assisting person scratch himself by this pointed end. Therefore the needle unit is stored in a magazine which covers the needle unit only leaving free the opening wherein the needle receiving part of the syringe shall be inserted.

It is the object of the invention to provide a magazine which may further be used for removing a used needle from the syringe and for keeping it locked in the magazine in a position so that the used needle may not be removed from the magazine after the reinsertion therein. Further it is the object of the invention to show appropriate modifications of the needle unit design which ensures a good collaboration between the needle unit and the magazine.

A magazine according to the invention is characterized in that it has a compartment having a bottom, a cylindric side wall, and an access opening, which compartment accommodates the needle unit with a gap between the outer side wall

of this needle unit and the inner side wall of the compartment, and that a circle of tongue shaped flexible protrusions at one end thereof are hinged at the inner surface of the side wall of the compartment and at their other end are free, the length of the protrusions exceeding the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.

When the needle unit is stored in the magazine the bottom of this magazine supports the needle hub when a needle receiving end of a syringe is pressed into the needle hub to mount this hub onto the syringe. When the needle hub is snap engaged to the syringe it may easily be drawn out of the magazine with the protrusions sliding along the cylindric outer surface of the needle hub. When a used needle unit is reinserted into the magazine the flexible protrusions will have assumed a position wherein the opening defined by the free end of the protrusion has a smaller diameter than has the cylindric part of the needle hub. When the hub is inserted the protrusions will be deflected with their free ends pointing toward the bottom of the compartment until these protrusions assume an oblique position where the cylindric part of the needle unit may pass the free ends of the protrusions which may now slide over the surface of the cylindric part during the further insertion of the needle unit into the magazine. When hereafter the syringe is retracted the protrusions will jam in the gap and retain the needle unit back in the magazine so that pulling the syringe and the magazine away from each other will result in a release of the snap engagement between the needle unit and the syringe.

Not to rely only on the jamming of the protrusions in the gap between the compartment wall and the needle unit the free end of the protrusion abutting the cylindric part of the needle unit may be sharpened so that they will cut into this cylindric part when an attempt is made to move this unit in a direction opposite the direction indicated by the protrusions.

The circle of sharp ended flexible protrusions may appropriately be provided as radially inward extending tongues in a metal ring fixed to the inner wall of the compartment of the magazine.

Due to the locking function of the protrusions the new needle units which are sold stored in the magazine may not just be inserted into the magazine as this would put the protrusion in their locking position. Therefore a special packing technique must be used to ensure that the protrusions of magazines with new needle units ready for use are pointing towards the access opening of the magazine. This may be obtained when the protrusions are provided on the inner surface of sleeve which as a lining is inserted and secured in the compartment. This construction allows that a new and unused needle unit is placed in the magazine whereafter the lining sleeve is inserted in the compartment through the access opening thereof. During the insertion of the lining the free ends of the protrusions will be deflected towards the access opening by the cylindric part of the needle unit already placed in the magazine. With this direction of the protrusions the needle unit may easily be drawn out of the magazine.

The collabpration of the locking means of the magazine and the cylindric part of the needle unit may be enhanced by appropriate design of said cylindric part. This design may consist in the provision of at least one circumferential edge on the cylindric wall of the needle unit. The edge may be drawn past the protrusions as long as these protrusions point away from the edge, but a jamming will occur when the ends of the protrusions abuts against the edge as the protrusion not only have to be deflected but must be crumbled to let the edge pass.

Such an edge may be provided by the ends of a number of circumferentially spaced axial ribs on the cylindric outer wall of the needle unit.

In another embodiment the cylindric part of the needle unit may be provided with a circumferential ring shaped protrusion to provide the circumferential edge.

In still another embodiment the circumferential edge may be provided as the edge of a circumferential recess in the cylindric part of the needle hub.

In the following the invention is further described with reference to the drawings, wherein

Figure 1 shows a sectional view of a not assembled embodiment of a magazine and needle according to the invention,

Figure 2 shows a sectional view of the embodiment in figure 1 assembled for storage,

Figure 3 shows a sectional view of the embodiment in figure 2 with the needle finally disposed of in the magazine,

Figure 4 shows a sectional view of another embodiment of a magazine with a stored needle unit,

Figure 5 shows a locking ring for the magazine shown in figure 4, and

Figure 6 shows an exploded view of an embodiment of a magazine with a needle before assembling.

In figure 1 is shown a magazine 1, a needle unit 2, and a locking sleeve 3 in a position ready to be assembled to store the needle unit in the magazine in a way making it possible to take the needle unit from the magazine and to reinsert the needle unit in the magazine for final disposal.

The needle unit 2 comprises an injection needle 4 carried in a needle hub comprising a bottom 5 which carries a cylindric sleeve 6 surrounding one end of the needle 4 and having at its inner surface protrusions 7 for engagement with recesses in a needle receiving part of a syringe. On its outer surface the sleeve 6 has a circumferential rib 8 exhibiting an edge 9 facing the open syringe receiving end of the sleeve.

The magazine 1 comprises a needle accommodating compartment 10, needle hub support ribs 21, and a sleeve accommodating compartment 12. The needle unit 2 is inserted in the magazine 1 with the end of the needle not surrounded by the sleeve 6 inserted in the compartment 10 and the bottom 5 of the needle hub abutting against the needle support ribs 21. Thereby the sleeve 6 will be centered in the compartment 12 leaving a uniform gap between the outer surface of the sleeve 6 and the inner surface of the cylindric wall of the compartment 12 allowing the locking sleeve 3 to be pressed in through an open end of the compartment 12.

The locking sleeve 3 has a cylindric wall 13 which is at its inner surface along a circle in a plane perpendicular to the axis of the sleeve 13 provided with tongue shaped projections 14 which are flexible in their connection to the inner wall of the locking sleeve 13 and which extend radially so that the circle defined by their free ends has a minor diameter than has the needle hub. Consequently, when the locking sleeve 3 is inserted in the gap between the needle hub and the inner wall of the compartment 12 the needle hub will abut the projections 14 and deflect them to adopt an oblique position with their free ends pointing towards the open end of the magazine as shown in figure 2. The locking sleeve 3 is secured in the compartment 12, e.g. by having a flange 15 which is received in a recess 16 surrounding the access opening of the magazine and a gluing or welding being established between the flange 15 and the recess 16. Alternatively an irreversible snap lock connection may be provided between the outer surface of the locking sleeve and the inner cylindric surface of the compartment 12.

When the needle unit 2 is positioned in the magazine 1 and the locking sleeve is inserted in the gap between the needle hub and the magazine the magazine is closed by a membrane 17 covering the access opening of the magazine and the needle unit may in this way be maintained sterile as long as it is stored in the magazine. The membrane may be made from paper which does not allow germs to pass but is permeable to hot steam used to sterilize the needle unit in the magazine.

When the needle unit is going to be used, the membrane 17 is removed and the needle receiving part of a syringe is inserted into the open end of the sleeve 6

and moved into this sleeve until the protrusions 7 engages the recesses in the needle receiving part of the syringe. When the syringe is retracted the needle unit will follow this syringe due to the snap connection between this needle unit and the syringe. The protrusion 8 of the needle hub may pass the tongues of the locking sleeve as these tongues are passed in a direction allowing them to be further deflected. When the needle unit is removed from the magazine the tongues will due to their flexibility return to a position with their free ends defining a circle having a diameter smaller than the diameter of the needle hub.

When after use the needle hub mounted on the syringe is reinserted in the magazine the needle hub will abut the tongues and deflect them to an oblique position with their free ends pointing away from the access opening of the magazine. During further insertion of the needle unit the protrusion 8 of this unit may pass the tongues and after this passing the needle unit is locked in the magazine as a retraction will cause the free ends of the tongues to abut against the edge 9 and consequently the force exerted on the tongues during a retraction of the needle unit is not a deflecting one but a force in the longitudinal direction of the tongues so that the tongues must be crumbled before the needle unit may be removed from the magazine. For such a crumbling a force is needed which far exceeds the force needed to release the snap connection between the needle unit and the syringe, and consequently the needle unit will remain in the magazine when the syringe is retracted.

In the shown embodiment the needle unit was designed for use with the magazine by having an edge 9 facing the access opening of the magazine. This edge 9 is provided on a circumferential protrusion 8 of the needle unit. The edge may alternatively be provided as end surfaces of circumferentially spaced ribs on the outer surface of the sleeve 6 or as an edge of a circumferential recess in this outer surface.

In a more universal embodiment of the magazine no special designed needle unit is demanded. In such an embodiment tongues 14 having a sharp free end are provided as radially inward pointing tongues of metal or a hard plastic. The sleeve

13 and the tongues 14 are preferably moulded as one integral part. However, if different materials are used for the sleeve and the tongues, a flat ring 18 is provided with radial inward pointing tongues 14 as shown in figure 5. This ring has a diameter corresponding to the diameter of the access opening of the magazine. When the needle unit is positioned in the magazine the ring is placed in the gap between the needle unit and the wall of the compartment 12 so that the needle hub deflects the tongues 14 to an oblique position with their free ends abutting the outer surface of the sleeve 6. The ring 18 is placed so it abuts a shoulder formed by ends of the needle hub supporting ribs 21 and is secured in this position by a sleeve 20 inserted from the access opening of the magazine as shown i figure 4. During the first removal and the reinsertion of the needle hub the tongues 14 will function in the same way as the tongues 14 in figure 1 - 3, but if an attempt is made to remove the reinserted needle unit from the magazine the sharp free end of the tongues will cut into the surface of the needle hub and provide a detent against removal of the needle unit. This function is not depending on the needle unit design and the protrusions 8 shown in figure 4 are not actually needed.

Figure 6 shows an exploded view of a magazine with a needle unit. In this figure it is seen that some of the tongues in the locking sleeve are replaced by axial guiding ribs 22 which abutting an outer circumferential surface of the needle unit contribute to the centering of the needle unit in the magazine.

Claims

1. A magazine for storing and final disposal of a snap-on needle unit carrying a needle mounted in a hub comprising a sleeve with an open end for insertion of a needle receiving part of a syringe and exhibiting a mainly cylindric outer wall, characterized in that the magazine has a compartment having a bottom, a cylindric side wall, and an access opening, which compartment accommodates the needle unit with a gap between the outer side wall of this needle unit and the inner side wall of the compartment, and that a circle of tongue shaped protrusions at one end thereof are hinged at the inner surface of the side wall of the compartment and at their other end are free, the length of the protrusions exceeding the width of the gap so that the protrusions are deflected to assume an oblique position with their free ends abutting the cylindric outer wall of the needle unit, the free ends pointing towards the access opening of the compartment when the unused needle is stored in the magazine and pointing towards the bottom of the compartment when the needle unit is reinserted in the magazine.

2. A magazine according to claim 1, characterized in that the free end of the protrusions abutting the cylindric part of the needle unit are sharpened.

3. A magazine according to claim 2, characterized in that the protrusions are provided as radially inward extending tongues in a metal ring fixed at the inner wall of the compartment of the magazine.

4. A magazine according to anyone of the claims 1 - 3, characterized in that the protrusions are provided on the inner surface of a sleeve which as a lining is inserted and secured in the compartment.

5. A needle hub for use in a magazine according to the claims 1-4, characterized in that on the mainly cylindric outer wall of the needle unit at least one circumferential edge is provided facing the open end of the sleeve.

6. A needle hub according to claim 5, characterized in that the edge is defined by the ends of a number of circumferential spaced axial ribs on the cylindric outer wall of the needle unit.

7. A needle hub according to claim 5, characterized in that the edge is provided by the cylindric outer wall of the needle unit being provided with a circumferential ring shaped protrusion.

8. A needle hub according to claim 5, characterized in that the edge is provided as an edge of a circumferential recess in the cylindric outer wall of the needle hub.

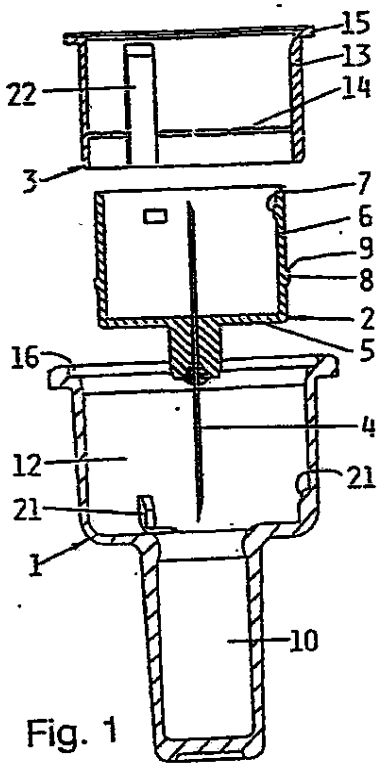

Fig. 1

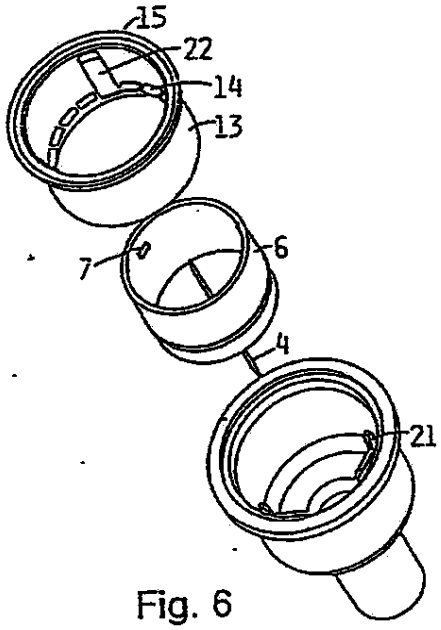

Fig. 6

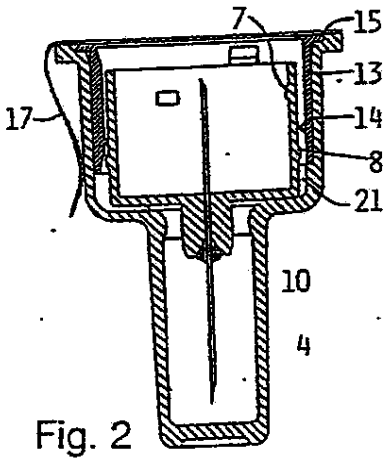

Fig. 2

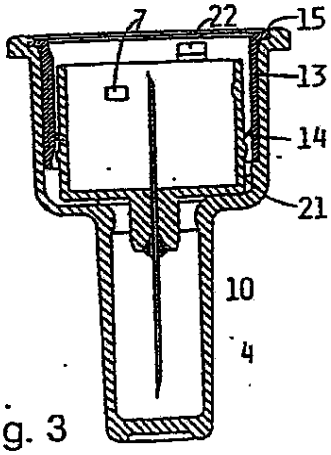

Fig. 3

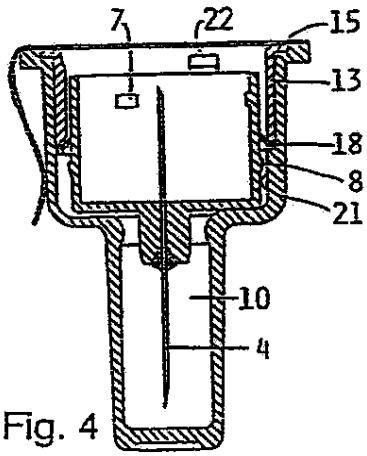

Fig. 4

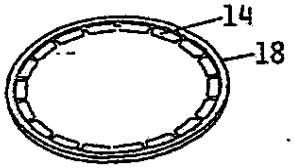

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 95/00306

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61M 5/32
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 8200412 A1 (ELISHA, BENJAMIN), 18 February 1982 (18.02.82), page 4, line 18 - line 27, figure 2	1-4
X	figure 3	5,7

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
10 October 1995	10-11-1995
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INTERNATIONAL SEARCH REPORT

Information on patent family members

28/08/95

International application No.
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 8200412	18/02/82	NONE	

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Publiée
Avec rapport de recherche internationale.

(54) Title: DISPENSING DEVICE WITH SAFE OPERATION CONTROL AND REFILL FOR SAME

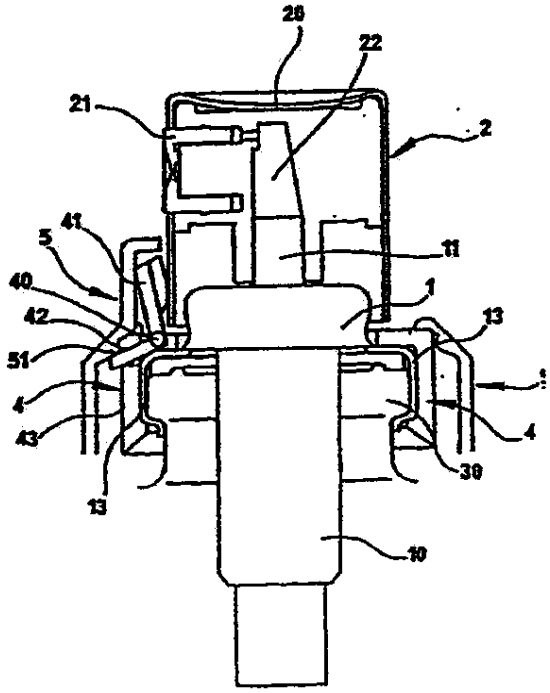
(54) Titre: DISPOSITIF DE DISTRIBUTION A SECURITE D'ACTIONNEMENT ET RECHARGE D'UN TEL DISPOSITIF

(57) Abstract

The invention discloses a dispensing device for a fluid product comprising a dispensing unit (1) provided with an axially movable control head (2) and a reservoir (3) containing the fluid to be dispensed, the said dispensing unit (1) being fixed on the reservoir (3), characterised in that the device further comprises means (4) for blocking any axial movement of the control head (2), and unlocking means (5) for engaging to the said blocking means (4) to cancel the action of the said blocking means (4) on the control head (2) and thus allow the axial movement of the said control head (2).

(57) Abrégé

Dispositif de distribution de produit fluide comprenant un organe de distribution (1) doté d'une tête d'actionnement (2) déplaçable axialement et d'un réservoir (3) contenant le produit fluide à distribuer, ledit organe de distribution (1) étant fixé sur le réservoir (3), caractérisé en ce que le dispositif comprend en outre des moyens de blocage (4) pour empêcher tout déplacement axial de la tête d'actionnement (2), et des moyens de déverrouillage (5) destinés à être mis en prise avec les moyens de blocage (4) pour effacer l'action desdits moyens de blocage (4) sur la tête d'actionnement (2) et ainsi permettre le déplacement axial de ladite tête d'actionnement (2).



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Dispositif de distribution à sécurité d'actionnement et recharge d'un tel dispositif.

La présente invention concerne un dispositif de distribution à sécurité d'actionnement ainsi qu'une recharge d'un tel dispositif. L'invention s'applique plus particulièrement au domaine de la parfumerie où le conditionnement du produit joue un rôle esthétique important. Le conditionnement peut représenter une certaine valeur et il est alors avantageux de pouvoir le rentabiliser. Des recharges peuvent alors être spécialement prévues pour ce type de conditionnement. L'application de l'invention dans le cadre d'un conditionnement réutilisable n'est qu'une mise en oeuvre préférentielle ; bien entendu, le dispositif de distribution à sécurité d'actionnement de l'invention peut être utilisé dans bien d'autres domaines tel que la cosmétique, la pharmacie, l'alimentation, la droguerie etc., sans application à un conditionnement réutilisable.

Il est déjà connu d'équiper certains dispositifs de distribution du type réservoir ou flacon muni d'un organe de distribution tel une pompe ou une valve, de sécurités d'actionnement ou de garanties de premier usage, afin d'assurer à l'utilisateur la primeur d'utilisation du dispositif. Ces sécurités ou garanties se présentent souvent sous la forme de bandes arrachables ou frangibles reliées à la tête d'actionnement du dispositif pour empêcher son actionnement. Une fois la bande arrachée ou détruite, la tête d'actionnement peut se déplacer axialement et distribuer le produit. Ce genre de sécurité ou garantie est basé sur le principe de l'immobilisation de la tête d'actionnement grâce à un élément à retirer ou à détruire.

L'arrachement ou la destruction de la bande nécessite une certaine force de traction qui peut parfois conduire au déchirement de la bande elle-même ; une partie de la bande reste alors en place, et il est difficile de la retirer complètement. En outre, la bande retirée constitue un déchet de petite taille dont il faut se débarrasser tout de même. Un autre inconvénient provient du fait que ce type de sécurité est irréversible, en ce sens que la bande ne peut plus être remise en place pour empêcher l'actionnement de la tête.

Un problème à la base de la présente invention est de réaliser un dispositif de distribution pourvu d'une sécurité d'actionnement fiable, non destructive, c'est-à-dire réversible, et dont la mise hors fonction s'effectue sans nécessiter une force particulière.

On connait déjà du document US-3 885 717 une sécurité à l'usage des enfants pour des bombes aérosols. La tête d'actionnement de la valve est pourvue de part et d'autre de pattes élastiques qui s'étendent vers le bas et dont les extrémités sont dotées de crochets qui viennent en prise sous la tête d'actionnement. Les pattes définissent ainsi ensemble un passage que le doigt doit obligatoirement emprunter pour accéder à la tête d'actionnement. Le doigt étant plus large que celui d'un enfant, seul le doigt d'un adulte est apte à s'engager dans le passage formé par les pattes élastiques en les repoussant de manière à dégager les crochets d'en dessous de la tête. Dans cette sécurité, le déverrouillage est effectué par le doigt de l'utilisateur et par conséquent tout adulte peut déverrouiller la bombe. Il ne s'agit donc pas d'une sécurité totale, mais uniquement sélective à l'égard des enfants. D'autre part, la largeur des doigts chez les adultes est très variable, de sorte que cette sécurité n'assure même pas la possibilité d'utilisation pour tous les adultes.

La présente invention a pour but de remédier à ces inconvénients en définisant une sécurité dite de premier usage non sélective dont le déverrouillage ne dépend pas de la nature de l'utilisateur.

Pour ce faire, il est prévu un dispositif de distribution de produit fluide comprenant un organe de distribution doté d'une tête d'actionnement déplacable axialement et d'un réservoir contenant le produit fluide à distribuer, ledit organe de distribution étant fixé sur le réservoir, caractérisé en ce que le dispositif comprend en outre des moyens de blocage pour empêcher tout déplacement axial de la tête d'actionnement, et des moyens de déverrouillage pour effacer l'action desdits moyens de blocage sur la tête d'actionnement et ainsi permettre le déplacement axial de ladite tête d'actionnement. Les moyens de déverrouillage assurent la mise hors fonction des moyens de blocage qui restent en place sur le dispositif.

Avantageusement, les moyens de blocage comprennent au moins un élément de blocage disposé dans le chemin de déplacement axial de la tête d'actionnement, ledit élément de blocage étant écarté du chemin de déplacement axial de la tête d'actionnement par lesdits moyens de déverrouillage.

Selon une forme de réalisation, ledit au moins un élément de blocage est monté pivotant et comprend une surface de came, lesdits moyens de déverrouillage venant en prise avec ladite surface de came pour écarter par pivotement ledit élément de blocage hors du chemin de déplacement axial de la tête d'actionnement.

De préférence, les moyens de blocage comprennent plusieurs éléments de blocage répartis à espacement angulaire régulier tout autour de la tête d'actionnement.

Alors que la mise hors fonction de la sécurité de l'art antérieur constituée d'une bande est simplement

réalisée par son arrachement ou sa destruction, dans la présente invention, les éléments de blocage sont écartés par pivotement sans destruction de sorte que le retrait des moyens de déverrouillage permet à nouveau aux éléments de blocage de reprendre leur position initiale dans le chemin de déplacement de la tête ; ceci assure la réversibilité de la sécurité d'actionnement.

Selon une forme pratique, les moyens de blocage se présentent dans la forme d'une bague de blocage montée fixement sur l'organe de distribution ou le réservoir, ladite bague de blocage étant pourvue à son extrémité supérieure desdits éléments de blocage pivotants, lesdits moyens de déverrouillage se présentant sous la forme d'une bague de déverrouillage rapportée sur la bague de blocage en sollicitant les éléments de blocage par pivotement vers l'extérieur hors du chemin de déplacement de la tête d'actionnement.

Les moyens de déverrouillage sont rapportés sur les moyens de blocage avec lesquels ils viennent ainsi en prise pour effacer leur action. De plus, les moyens de déverrouillage agissent sur les moyens de blocage indépendamment de l'actionnement de la tête d'actionnement. Le déverrouillage n'est pas effectué par le doigt de l'utilisateur comme dans le document US-3 885 717 mais par un organe rapporté qui n'agit sur la tête d'actionnement.

Selon une caractéristique très avantageuse de la présente invention, le dispositif comprend en outre un étui dans lequel le réservoir est introduit, les moyens de déverrouillage connectant ledit étui de manière démontable, de sorte que le réservoir équipé de son organe de distribution peut être introduit et extrait de l'étui en tant que recharge, la connexion des moyens de déverrouillage sur l'étui mettant lesdits moyens de

déverrouillage en prise avec les moyens de blocage pour les déverrouiller.

Dans cette application préférentielle de l'invention, le réservoir équipé de son organe de distribution constitue une recharge pour un étui dont la partie supérieure de fermeture est constituée par les moyens de déverrouillage qui opèrent à la fois le déverrouillage des moyens de blocage et la fermeture de l'étui. Cette forme de réalisation est particulièrement avantageuse, car l'utilisateur n'a même pas besoin d'effectuer une opération particulière pour effacer l'action des moyens de blocage qui se fait automatiquement lors de l'encliquetage des moyens de déverrouillage sur l'étui.

Ainsi, il n'est même pas nécessaire d'informer l'utilisateur que la recharge incorpore une sécurité d'actionnement. De plus, si l'utilisateur souhaite bloquer l'actionnement du dispositif pendant un certain temps, il lui suffit de retirer légèrement les moyens de déverrouillage et les éléments de blocage reprendront leur place initiale sous la tête d'actionnement.

L'invention définit également une recharge de dispositif de distribution de produit fluide comprenant un organe de distribution doté d'une tête d'actionnement déplaçable axialement et d'un réservoir contenant le produit fluide à distribuer, ledit organe de distribution étant fixé sur le réservoir, caractérisé en ce que la recharge comprend en outre des moyens de blocage pour empêcher tout déplacement axial de la tête d'actionnement, lesdits moyens de blocage étant destinés à être déverrouillés à l'aide de moyens de déverrouillage faisant partie d'un ensemble de conditionnement destiné à recevoir ladite recharge. La recharge peut être achetée dans le commerce, équipée de sa sécurité d'actionnement, ce qui assure la primeur d'utilisation. L'ensemble de conditionnement est réutilisable et comprend un étui et

les moyens de déverrouillage qui viennent former l'étui en ne laissant passer que la tête d'actionnement.

L'invention sera maintenant décrite plus amplement en référence aux dessins joints, donnant à titre d'exemple non limitatif plusieurs modes de réalisation de l'invention.

Sur les dessins :

- la figure 1 représente la partie supérieure d'un dispositif de distribution selon l'invention avec les moyens de blocage en position de blocage, des moyens de déverrouillage étant omis,
- la figure 2 représente un dispositif de distribution de la figure 1 avec les moyens de déverrouillage en prise avec les moyens de blocage de manière à permettre le déplacement de la tête d'actionnement,
- la figure 3 représente une forme préférentielle de réalisation d'un dispositif de distribution selon l'invention, les moyens de blocage étant en position de blocage et les moyens de déverrouillage étant omis,
- la figure 4 est une vue du dispositif de distribution de la figure 3 avec les moyens de déverrouillage en prise avec les moyens de blocage de manière à libérer la tête d'actionnement dans son déplacement axial, et
- la figure 5 est une vue agrandie en coupe des moyens de blocage utilisé dans le dispositif de distribution représenté sur les figures 3 et 4.

En se référant d'abord aux figures 1 et 2, on voit que le dispositif de distribution selon cette première forme de réalisation ne représente que la partie supérieure du dispositif, seul le goulot 30 du réservoir étant représenté. Outre le réservoir qui peut être rigide ou souple, en matière plastique en verre ou en métal, le dispositif de distribution de l'invention comprend un organe de distribution désigné dans son ensemble par la référence numérique 1. Cet organe de distribution 1 qui

peut être une pompe ou une valve, comprend un corps de pompe 10 engagé dans le goulot 30 du réservoir. L'organe de distribution est serti par la partie supérieure de son corps 10 sur le goulot 30 à l'aide d'un sertissage 13. De manière classique, un joint peut être interposé entre le goulot 30 et le sertissage 13 pour assurer l'étanchéité du dispositif au niveau du goulot du réservoir. L'organe de distribution comprend en outre une tige d'actionnement 11 qui est montée coulissante dans le corps 10 de l'organe de distribution 1. La tige d'actionnement 11 est creuse et constitue ainsi un canal de refoulement du produit fluide mis sous pression dans le corps 10. Pour l'actionnement de la tige 11, il est prévu une tête d'actionnement désignée dans son ensemble par la référence numérique 2. La tête d'actionnement 2 comprend un canal interne 22 en communication avec l'intérieur de la tige d'actionnement 11 ainsi qu'avec un gicleur 21 destiné à pulvériser le produit fluide en fines gouttelettes. La tête d'actionnement 2 comprend également une surface de pression 20 adaptée à l'application d'un doigt par exemple. Une pression sur la surface 20 de la tête d'actionnement 2 amène la tête et la tige 11 à se déplacer axialement, comme on peut le voir sur les figures 1 et 2. Dans le cas d'une pompe, l'enfoncement de la tige 11 a pour effet de mettre la chambre de pompe comprise dans le corps de pompe 10 sous pression jusqu'à ce que le clapet de sortie de la pompe s'ouvre et refoule la dose de produit fluide à travers l'intérieur creux de la tige d'actionnement 11 jusqu'au gicleur 21 où la dose de produit fluide est pulvérisée. Dans le cas d'une valve, l'enfoncement de la tige de soupape 11 a pour effet de mettre en communication fluide l'intérieur du réservoir ou une partie de celui-ci avec l'extérieur à travers l'intérieur creux de la tige de soupape 11 jusqu'au gicleur 21 où le produit fluide est pulvérisé. Dans les

deux cas, qu'il s'agisse d'une pompe ou d'une valve, la distribution du produit fluide est réalisé grâce au déplacement axial de la tige d'actionnement 11 surmontée de son bouton poussoir 2 incorporant le gicleur 21.

Cette conception générale du dispositif de distribution selon l'invention est commune à toute les formes de réalisation décrite.

En se référant maintenant plus particulièrement à la figure 1, on voit que le goulot 30 du réservoir, ou plus précisément le sertissage 13 de l'organe de distribution, est recouvert par une pièce désignée dans son ensemble par la référence numérique 4 qui sert de moyen de blocage pour la tête d'actionnement 2. Cette pièce 4 réalisant un moyen de blocage comprenant une bague de blocage formée avec des pattes d'encliquetage 43 terminée par des dents d'encliquetage 46 qui sont en prise avec le goulot 30 du réservoir. Les pattes d'encliquetage 43 munies de leurs dents 46 permettent une fixation solide et stable de la pièce 4 sur le goulot 30. La bague de blocage 4 s'étend jusqu'au dessus du goulot 30 où elle est pourvue d'éléments de blocage 41 qui sont disposés dans le chemin de déplacement axial de la tête d'actionnement 2 pour bloquer la tête d'actionnement 2 en position de repos. Les éléments de blocage 41 sont répartis tout autour de la bague de blocage 4 dans le chemin de déplacement axial de la tête d'actionnement 2. Les éléments de blocage 41 peuvent au nombre de trois ou de six mais il est également envisageable de ne prévoir qu'un seul élément de blocage 41 sur la bague de blocage 4. Les éléments de blocage 41 sont montés pivotants sur la bague 4 autour d'un axe de pivotement 40. Pour permettre le pivotement des éléments de blocage 41, il est prévu une surface de came 42 qui est reliée à l'élément de blocage 41 de manière rigide de sorte qu'une pression exercée sur la surface de came 42 provoque le pivotement de l'élément de blocage 41 autour

de l'axe de pivotement 40. Comme on peut le voir sur la figure 1, les axes de pivotement 40 s'étendent de manière tangentielle à la bague de blocage 4, de sorte que la direction de pivotement de l'élément de blocage 41 s'étend radialement par rapport à la tige d'actionnement 11. Dans la position de repos de la bague de blocage 4, les éléments de blocage 41 sont disposés dans le chemin de déplacement axial de la tête d'actionnement 2. Afin d'assurer que les éléments de blocage sont correctement disposés en dessous de la tête d'actionnement 2, les éléments de blocage 41 sont pourvu d'un épaississement 410, qui augmente considérablement la surface de butée de l'extrémité inférieure de la tête d'actionnement 2 sur l'extrémité supérieure des éléments de blocage 41. Ainsi, grâce à l'interposition des éléments de blocage 41 en dessous de la tête d'actionnement 2, tout déplacement axial de la tête de et par conséquent de la tige d'actionnement 11, est empêché. Le dispositif de distribution ne peut alors pas être actionner de sorte qu'aucune dose de produit fluide ne peut être émise.

En se référant maintenant à la figure 2, il va être expliquer de quelle manière les éléments de blocage 41 sont déplacés hors du chemin de déplacement axial de la tête d'actionnement 2. Comme on peut le voir sur la partie gauche de la figure 2, les éléments de blocage 41 sont écartés hors du chemin de déplacement axial de la tête d'actionnement 2 à l'aide d'une bague de déverrouillage désignée dans son ensemble par la référence numérique 5. La bague de déverrouillage comprend une surface d'appui 51 qui coopère avec la surface de came 42 de l'élément de blocage 41 de manière à abaisser la surface de came 42. L'abaissement de la surface de came 42 provoque le pivotement de l'élément de blocage 41 vers l'extérieur en éloignement de la tige d'actionnement 11. La bague de déverrouillage 5 doit donc être emmanchée sur la bague de

blocage 4 jusqu'à ce que la surface d'appui 51 de la bague de déverrouillage 5 sollicite la surface de came 42 de l'élément de blocage 41 vers le bas. Le maintien en place de la bague de déverrouillage 5 peut être réalisée grâce à un encliquetage de la bague 5 sur la bague 4 ou sur une autre partie du réservoir. Ainsi, la mise en place de la bague de déverrouillage 5 sur la bague de blocage 4 a pour effet d'écarter les éléments de blocage 41 hors du chemin de déplacement axial de la tête d'actionnement 2. Comme visible sur la figure 2, la tête d'actionnement peut alors être déplacée vers le bas, ce qui a pour effet d'émettre du produit fluide par le gicleur 21.

Il est à noter que l'utilisation d'une bague de déverrouillage 5 pour effacer l'action des éléments de blocage préserve la réversibilité de la fonction de blocage des éléments de blocage 41 par simple retrait de la bague de déverrouillage. En effet en retirant la bague de déverrouillage 5, la surface de came 42 n'est plus sollicitée vers le bas par la surface d'appui 51 de la bague 5, ce qui a pour effet de faire pivoter les éléments de blocage 41 à nouveau dans le chemin de déplacement axial de la tête d'actionnement 2. Il est donc possible grâce à l'invention de remettre le dispositif de distribution à nouveau en sécurité par simple retrait de la bague de déverrouillage 5, ce qui n'était pas possible avec les dispositifs de sécurités ou de garanties de l'art antérieur qui impliquait une destruction des éléments de blocage.

En référence aux figures 3 et 4, il sera maintenant décrit un mode de réalisation et d'application préférentiel de la présente invention. Le caractère préférentiel tient plus à la mise en application du dispositif de distribution qu'à sa forme de réalisation particulière. Dans cette forme de réalisation et d'application, l'ensemble constitué du réservoir 3 et de

son organe de distribution associé 1 surmonté de la tête d'actionnement 2 constitue une recharge destinée à être placée dans un ensemble de conditionnement constitué d'un étui 7 enveloppant partiellement le réservoir 3, d'un manchon de liaison 6 et de la bague de déverrouillage 5. La recharge pourra être achetée dans le commerce déjà équipé de sa bague de blocage 4 assurant la sécurité de premier usage, afin de garantir la primeur d'utilisation à l'acheteur du produit. Tout comme la bague de blocage de la forme de réalisation des figures 1 et 2, la bague de blocage de cette forme de réalisation préférentielle est monté fixement sur un bossage périphérique annulaire réalisé par le goulot du réservoir 3 recouvert par le sertissage 13 de l'organe de distribution 1. Dans son état encore non monté dans l'ensemble de conditionnement, et disponible tel quel dans le commerce la recharge ne peut pas être actionnée en raison de l'interposition des éléments de blocage 41 en dessous de la tête d'actionnement 2.

En se référant maintenant à la figure 4, la recharge est représentée introduite dans un ensemble de condition dont la partie supérieure de fermeture est réalisée par la bague de déverrouillage 5. La bague de déverrouillage 5, comme dans le mode de réalisation représenté sur les figures 1 et 2, sollicite les éléments de blocage 41 par pivotement vers l'extérieur hors du chemin de déplacement axial de la tête d'actionnement 2. Le pivotement vers l'extérieur des éléments de blocage 41 est réalisé par appui de la bague de déverrouillage 5 sur les surfaces de came 42 solidaires des éléments de blocage 41.

Le détail de réalisation de la bague de blocage 4 sera décrit plus précisément en référence à la figure 5 ci-après. La bague de déverrouillage 5 coopère donc d'une part avec les surfaces de came 42 des éléments de blocage 41 ainsi qu'avec un manchon de transition 6 qui lui est

encliqueté dans l'extrémité supérieure ouverture de l'étui 7. La connexion de la bague de déverrouillage 5 sur l'extrémité supérieure du manchon de transition 7 peut être du type encliquetage, emmanchage en force ou même vissage. L'ensemble de condition réalisé par les éléments constitutifs 5, 6 et 7 recouvrent la totalité de la recharge à l'exception de la tête d'actionnement 2 qui doit rester accessible en vue de son actionnement.

Dans cette application en tant que recharge pour un ensemble de conditionnement réutilisable, l'effacement des éléments de blocage 42 est réalisé de manière automatique lors de la fermeture de l'ensemble de conditionnement en rapportant simplement la bague de déverrouillage sur le manchon de transition 6. Ainsi, en une seule opération l'ensemble de condition est reconstitué et la sécurité d'actionnement est effacée.

La figure 5 représente une section agrandie de la bague de blocage utilisée dans la recharge représentée sur les figures 3 et 4. La bague de blocage 4 est formée avec les pattes d'encliquetage 43 pourvues d'un évidemment périphérique annulaire 46 destiné à recevoir le bossage périphérique formé par le goulot 30 du récipient 3. Les pattes d'encliquetage 43 sont surmontées par les éléments de blocage 41 pourvus de leurs surfaces de came 42. Alors que dans la forme de réalisation des figures 1 et 2 le pivotement des éléments de blocage 4 était réalisé grâce à un axe de pivotement 40, dans cette forme de réalisation, le pivotement des éléments de blocage 41 est assuré par un pont de matière 45 qui relie les éléments de blocage 41 au restant de la bague. Les ponts de matière présentent une section réduite de manière à créer une zone de faiblesse définissant un point d'articulation. Le nombre d'élément de blocage 41 répartie tout autour de la bague de blocage peut être variable, mais en général ils seront au nombre de 3 à 6.

Revendications :

1.- Dispositif de distribution de produit fluide comprenant un organe de distribution (1) doté d'une tête d'actionnement (2) déplaçable axialement et d'un réservoir (3) contenant le produit fluide à distribuer, ledit organe de distribution (1) étant fixé sur le réservoir (3), caractérisé en ce que le dispositif comprend en outre des moyens de blocage (4) pour empêcher tout déplacement axial de la tête d'actionnement (2), et des moyens de déverrouillage (5) pour effacer l'action desdits moyens de blocage (4) sur la tête d'actionnement (2) et ainsi permettre le déplacement axial de ladite tête d'actionnement (2).

2.- Dispositif de distribution selon la revendication 1 dans lequel les moyens de blocage (4) comprennent au moins un élément de blocage (41) disposé dans le chemin de déplacement axial de la tête d'actionnement (2), ledit élément de blocage (41) étant écarté du chemin de déplacement axial de la tête d'actionnement (2) par lesdits moyens de déverrouillage (5).

3.- Dispositif de distribution selon la revendication 2 dans lequel ledit au moins un élément de blocage (41) est monté pivotant et comprend une surface de came (42), lesdits moyens de déverrouillage (5) venant en prise avec ladite surface de came (42) pour écarter par pivotement ledit élément de blocage (41) hors du chemin de déplacement axial de la tête d'actionnement (2).

4.- Dispositif de distribution selon les revendications 1 ou 2 dans lequel les moyens de blocage (4) comprennent plusieurs éléments de blocage (41) répartis à espacement angulaire régulier tout autour de la tête d'actionnement (2).

5.- Dispositif de distribution selon la revendication 4 dans lequel les moyens de blocage se présentent dans la

forme d'une bague de blocage (4) montée fixement sur l'organe de distribution (1) ou le réservoir (3), ladite bague de blocage (4) étant pourvue à son extrémité supérieure desdits éléments de blocage pivotants (41), lesdits moyens de déverrouillage se présentant sous la forme d'une bague de déverrouillage (5) rapportée sur la bague de blocage (4) en sollicitant les éléments de blocage (41) par pivotement vers l'extérieur hors du chemin de déplacement de la tête d'actionnement (2).

6.- Dispositif de distribution selon l'une quelconque des revendications précédentes, dans lequel les moyens de déverrouillage sont rapportés sur les moyens de blocage avec lesquels ils viennent ainsi en prise pour effacer leur action.

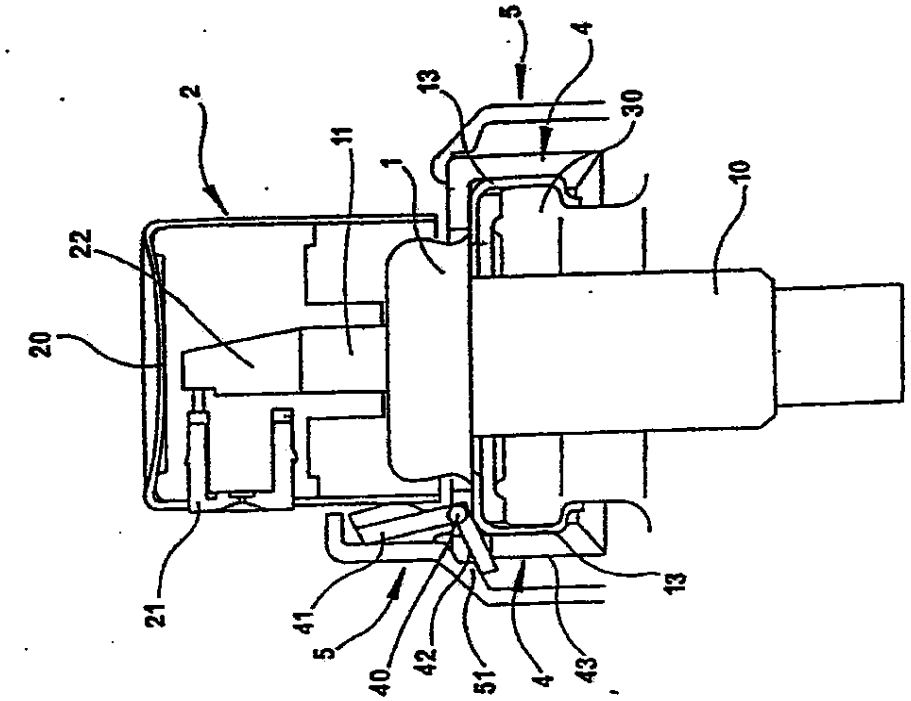
7.- Dispositif de distribution selon l'une quelconque des revendications précédentes, dans lequel les moyens de déverrouillage agissent sur les moyens de blocage indépendamment de l'actionnement de la tête d'actionnement.

8.- Dispositif de distribution selon l'une quelconque des revendications précédentes, dans lequel le dispositif comprend en outre un étui (7) dans lequel le réservoir (3) est introduit, les moyens de déverrouillage (5) connectant ledit étui (7) de manière démontable, de sorte que le réservoir (3) équipé de son organe de distribution (1) peut être introduit et extrait de l'étui (7) en tant que recharge, la connexion des moyens de déverrouillage (5) sur l'étui (7) mettant lesdits moyens de déverrouillage (5) en prise avec les moyens de blocage (4) pour les déverrouiller.

9.- Dispositif de distribution selon la revendication 8, dans lequel les moyens de déverrouillage (5) sont encliquetés sur l'étui (7), l'encliquetage opérant simultanément le déverrouillage des moyens de blocage (4).

10.- Recharge de dispositif de distribution de produit fluide comprenant un organe de distribution (1) doté d'une tête d'actionnement (2) déplaçable axialement et d'un réservoir (3) contenant le produit fluide à distribuer, ledit organe de distribution (1) étant fixé sur le réservoir (3), caractérisé en ce que la recharge comprend en outre des moyens de blocage (4) pour empêcher tout déplacement axial de la tête d'actionnement (2), lesdits moyens de blocage (4) étant destinés à être déverrouillés à l'aide de moyens de déverrouillage (5) faisant partie d'un ensemble de conditionnement destiné à recevoir ladite recharge.

1/2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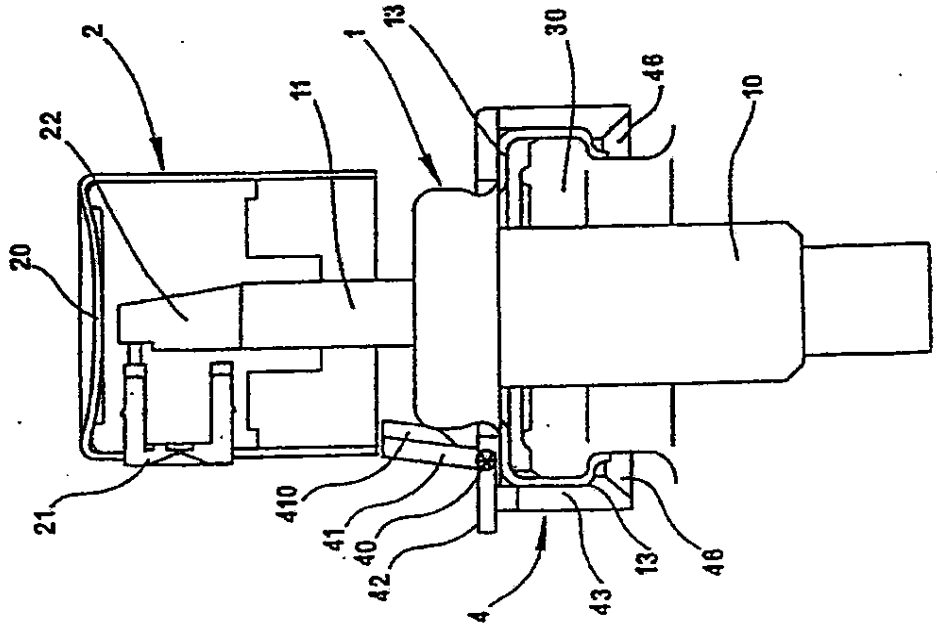
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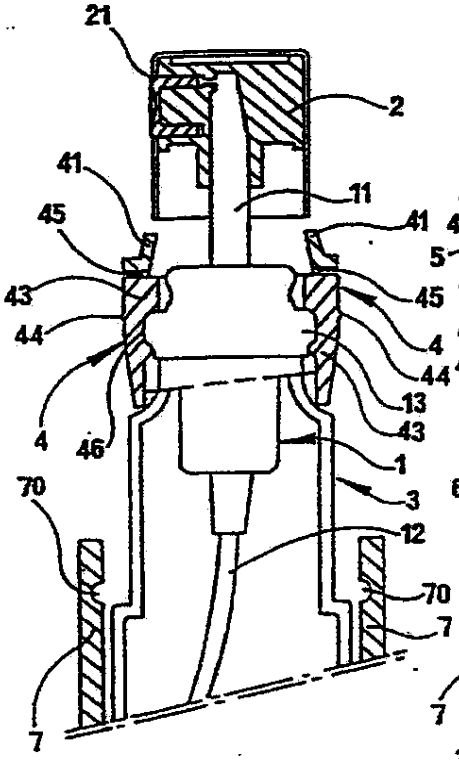

FIG.3

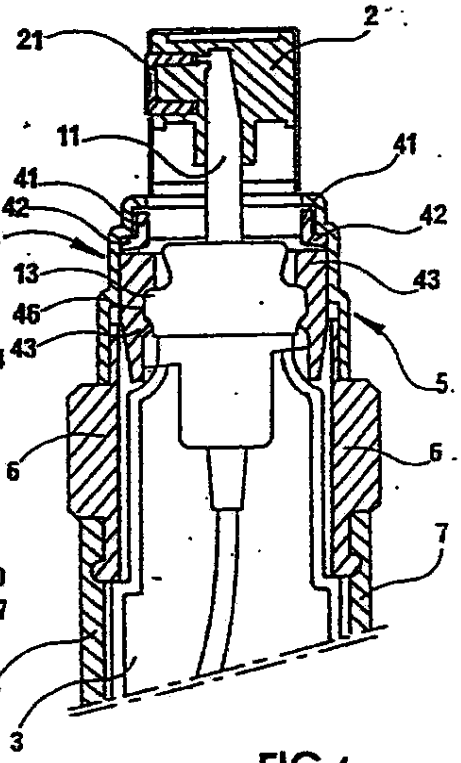

FIG.4

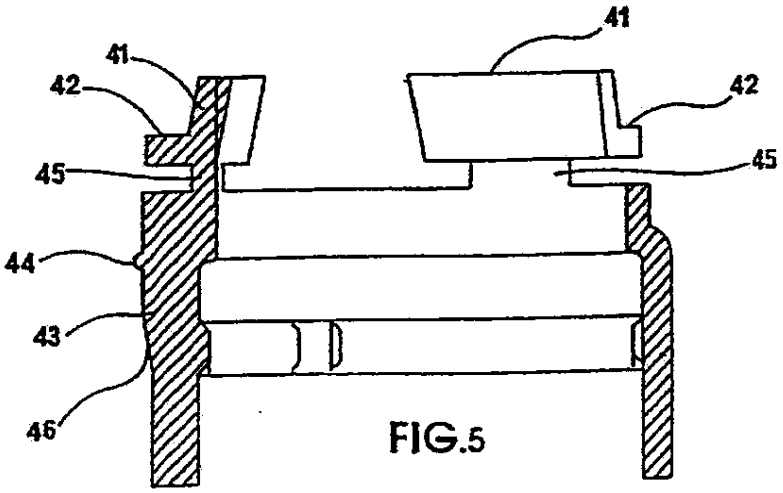

FIG.5

INTERNATIONAL SEARCH REPORT

Inter. anal Application No
PCT/FR 97/01064

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 B65D83/14 B05B11/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 B65D B05B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 885 717 A (EWALD RONALD F) 27 May 1975 see column 5, line 37 - column 5, line 53 see figures 5,6	1,10
A	US 3 606 106 A (YUHAS EDWARD R) 20 September 1971 see column 1, line 33 - column 2, line 23 see figures 1,2	1,10
A	EP 0 168 285 A (TELEPLASTICS IND) 15 January 1986 see abstract see figures 4,4A	1,10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 September 1997	10.09.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Farizon, P

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter...onal Application No
PCT/FR 97/01064

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		DE 2418720 A	31-10-74
		FR 2226330 A	15-11-74
		GB 1442607 A	14-07-76
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EP 0168285 A	15-01-86	FR 2565799 A	20-12-85
		DE 3562007 A	05-05-88
		US 4676408 A	30-06-87

RAPPORT DE RECHERCHE INTERNATIONALE

Dem. internationale No
PCT/FR 97/01064

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 6 B65D83/14 B05B11/00

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 6 B65D B05B

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si cela est réalisable, termes de recherche utilisés)

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
A	US 3 885 717 A (EWALD RONALD F) 27 mai 1975 voir colonne 5, ligne 37 - colonne 5, ligne 53 voir figures 5,6	1,10
A	US 3 606 106 A (YUHAS EDWARD R) 20 septembre 1971 voir colonne 1, ligne 33 - colonne 2, ligne 23 voir figures 1,2	1,10
A	EP 0 168 285 A (TELEPLASTICS IND) 15 janvier 1986 voir abrégé voir figures 4,4A	1,10

☐ Voir la suite du cadre C pour la fin de la liste des documents

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"&" document qui fait partie de la même famille de brevets

Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
5 septembre 1997	10.09.97

Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
Office Européen des Brevets, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tél. (+ 31-70) 340-2040. Tx. 31 651 epo nl. Fax (+ 31-70) 340-3016	Farizon, P

RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Demande internationale No
PCT/FR 97/01864

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
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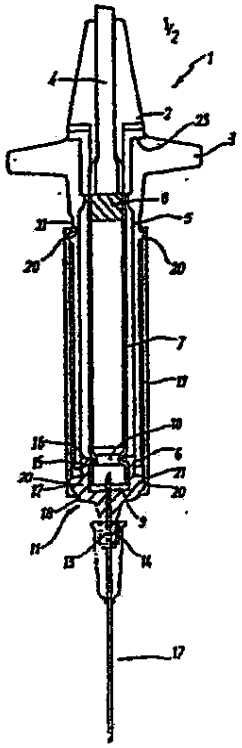
(54) Title: SYRINGES

(57) Abstract

A syringe has a drug-containing cartridge (7) with a bung (8) at one end which is engaged by a plunger (4), and a membrane (9) at its other end which is penetrated by a needle. A connecting structure (11) is connected to (or is formed integrally with) the needle (17) and fits onto the forward end of the cartridge (7) and the syringe. After use the cartridge (7), the connecting structure (11) and the needle (17) can be disposed together. A sleeve (19) is slidably mounted on the structure (11) and can be moved to sheath the needle (17).



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SYRINGES

This invention relates to syringes.

A conventional syringe, e.g. as used by a dentist to administer anaesthetic, has a barrel with a plunger mechanism at one end and a threaded connector for a needle at the opposite end. A drug-containing glass cartridge is inserted into the barrel, the needle is screwed onto the connector so that it penetrates a seal at the forward end of the cartridge, and the plunger mechanism is operated to engage a bung at the rearward end of the cartridge and thereby expel the drug through the needle. After use, the needle and cartridge are removed and discarded.

In order to minimise contamination problems, European Application EP 0394295-A describes a syringe in which, in place of the above mentioned cartridge, there is a drug-containing housing which is attached directly to the needle at one end and to the plunger mechanism at the other end. After use the entire housing, including the needle, is detached from the plunger mechanism and discarded thereby avoiding the need to sterilise the barrel and needle connector of the conventional syringe.

Whilst this arrangement provides an effective solution to contamination problems, it is necessary for the specially-constructed detachable housing to be pre-filled with the drug which can be inconvenient from a manufacturing point of view.

An object of the present invention is to provide a disposable syringe housing which is convenient to manufacture.

According to one aspect of the invention therefore there is provided a detachable housing for a syringe comprising a drug-containing cartridge having a bung at one end and a penetrable member at the other end, the cartridge being adapted for connection to a needle at the said other end, such that the needle penetrates the penetrable member, and being adapted for connection to a plunger mechanism at the said one end, so that the bung can be moved down the cartridge to expel the drug through the needle, characterised in that the cartridge is provided with at least one separate structure attachable relative thereto, said structure being adapted for the said connection of the cartridge to the needle and providing means for releasable connection to the plunger mechanism, whereby the housing comprising the cartridge, the (or each) said structure, and the needle can be detached from the plunger mechanism for disposal together.

With this arrangement the advantages of disposability can be attained with an arrangement which is particularly simple and convenient to manufacture in so far as it involves the use of a simple drug-containing cartridge which may be of the kind used with conventional syringes.

Most preferably there is one said structure which is attachable to the said other end of the cartridge and which is adapted for connection to the needle and which provides the means for connection to the plunger mechanism.

Thus, and in accordance with a second aspect of the present invention there is provided a structure for attachment to a drug-containing

cartridge of a syringe, which cartridge has a bung at a rearward end and a penetrable membrane at a forward end, said structure being adapted for attachment to a needle and having means for attachment relative to the forward end of the cartridge, and means for attachment to a plunger mechanism.

The means for attachment to the cartridge may comprise a clip or constriction or the like which fits around a neck at the forward end of the cartridge, such neck being a feature of conventional cartridges.

The structure may be formed integrally with the needle or alternatively it may incorporate means for connection to the needle which may comprise a threaded boss or nipple.

The means for attachment to the plunger mechanism may comprise an outer peripheral retaining structure, such as a screw-thread, adapted to mate with a corresponding retaining structure at the end of a barrel extension on the plunger mechanism, which extension fits around the cartridge from the rearward to the forward end thereof.

The barrel extension may have a longitudinally movable sleeve which can be moved forwardly to sheath the needle after use. This sleeve may be removable and disposable with the housing.

If desired, provision may be made for aspiration, or slight suck back with the syringe so that it can be seen if a vein or atery has been penetrated, such penetration being revealed by suck back of blood.

Thus, the said structure may be provided with a spring arrangement

which acts to urge the cartridge in a direction away from the needle, in conjunction with a releasable retention device bearing on the top rim of the cartridge. The spring arrangement may comprise a projection engageable with the resilient penetrable member of the cartridge, or an interposed spring means.

The invention will now be described further by way of example only and with reference to the accompanying drawings in which:

Fig. 1 is an axial section of a syringe provided with one form of a disposable housing in accordance with the invention; and

Figs. 2 & 3 are enlarged axial sections of a bottom part of the arrangement of Fig. 1 showing alternative embodiments thereof.

Referring to Fig. 1, the syringe comprises a plunger mechanism 1 (e.g. of stainless steel) having a body part 2 with a finger grip 3, a plunger 4 slidable axially through a bore in the body 2, and a barrel extension 5 coaxial with the plunger 4. The barrel extension 5 may comprise a tube, or apertured tube, or tubular framework.

At its forward end, the tubular extension 5 has an internal screw-thread 6.

A conventional drug-containing cartridge 7 is used with the syringe, such cartridge comprising a glass tube with a bung 8 within one (rearward) end and a foil covered penetrable membrane 9 across the other (forward) end. The glass tube is shaped to provide a circumferential groove 10 defining a neck close to the forward end.

A connection structure 11 is attached to the forward end of the cartridge 7. This structure 11 comprises a plastics body of cup-shaped form with a cylindrical part 12 which is closed at one end and has a central axially projecting boss 13 on its outer face.

There is a narrow axial bore through the closed end and the boss 13. The boss 13 and the cylindrical part 12 both have external screw-threads 14, 15.

The cylindrical part 12 has an open end bounded by an inturned lip 16.

There is sufficient resilience in the lip 16 and/or the associated body of the connection structure 11 to enable the structure to be pushed over the forward end of the cartridge 7 so that the lip 16 springs into, or snap fits with, the groove 10 thereby to retain the structure 11 securely on the end of the cartridge 7.

With the connection structure 11 in position the cartridge 7 can be inserted into the barrel extension 5 and held securely in position by screwing the thread 15 of the cylindrical part 12 into engagement with the screw thread 6 at the end of the barrel extension 5.

A conventional needle 17 can then be screwed on to the boss 13 so that its rear end penetrates the membrane 9.

In this position the rearward end of the cartridge 7 is at the rearward end of the barrel extension 5 and the bung 8 is close to the end of the plunger 4.

The syringe can now be operated in the usual way to cause the bung 8 to be displaced down the cartridge 7 with the plunger 4 to expel drug through the needle 17.

After use, the connection structure 11 is unscrewed from the barrel extension 5 so that the cartridge 7, connection structure 11, and needle 17 can be removed and disposed together.

It will be seen that the cylindrical part 12 of the connection structure 11 has a lower, or forward portion 18 which is not threaded and which remains outside the barrel extension 5 to provide a convenient finger grip for screwing and unscrewing the structure 11. This portion 18 may be enlarged or shaped as desired to further facilitate gripping.

As shown in Fig. 1 a tubular sleeve 19 may be engaged around the connection structure 11, such sleeve 19 being movable axially between a rearward limit position (as shown) at which it overlies the barrel extension 5 and fully exposes the needle 17, and a forward limit position at which it covers the needle 17.

The sleeve 19 is removed and disposed together with cartridge 7 and needle 17 with the sleeve 19 covering the needle 17 to avoid needle stick injuries.

The sleeve 19 has inwardly directed recesses 20 at each end which snap fit with projections 21 on the structure 11 to hold the sleeve 19 in each limit position. Also, the sleeve 19 may be internally longitudinally grooved to accommodate the projections 21 whereby the sleeve 19 is free

to move axially but cannot rotate relative to the structure 11. The rotation of the structure 11 relative to barrel extension 5 can therefore be effected by rotation of the sleeve 19.

With the arrangement described above, full advantages of disposability can be attained using a conventional cartridge.

As shown in the modified embodiment of Fig. 2, the structure 11 has an upstanding small projection 22 which presses against the penetrable membrane 9 at the end of the cartridge. At the top end of the syringe there is a suitable structure (indicated diagrammatically at 23 in Fig. 1) which bears against the top rim of the cartridge and holds the projection 22 pressed firmly into the membrane 9.

If this top end bearing structure 23 is now released, and pressure is released from the plunger 4, the cartridge will move slightly upwards due to the resilience of the membrane 9. This gives a very small suck-back or aspiration effect through the needle.

This is useful e.g. in dentistry where an injection is being made into soft gum tissue and it is desired to avoid penetration of a vein or artery. If penetration of a vein or artery has occurred the aspiration will cause blood to flow back into the cartridge.

Other resilient or spring arrangements may be used to achieve aspiration. Thus, Fig. 3 shows a modification in which the structure 11 is formed integrally with the needle 17. Springy transverse projections 24 or fingers are incorporated for resilient engagement with the bottom of the

cartridge.

It is of course to be understood that the invention is not intended to be restricted to the details of the above embodiment which are described by way of example only.

Thus, for example, the embodiment of Fig. 1 utilises a conventional needle and therefore has said connection structure 11 which is separate from the needle and is adapted to be interconnected thereto by means of the threaded boss 13. However, if desired, and as shown in Fig. 3, the structure 11 may be formed integrally with the needle so that it is supplied together with the needle.

Where the structure 11 is interconnected by means of the threaded boss 13 with a conventional needle, the structure 11 may be supplied with the needle, or ready fitted on the end of the cartridge or as a separate part to be fitted to the needle and to the cartridge prior to use.

The syringe may be as described adapted for end loading of the cartridge. It is however also possible to use a conventional side-loading syringe. The body of the syringe may be formed from plastics or stainless steel or any other suitable material or combination of materials as appropriate.

The interconnection between the structure 11 and the syringe body need not be through screw threads. Especially in the case of a rigid stainless steel syringe body, the interconnection may be achieved in the manner of a push-in or snap-fit or other clip type connection.

Depending on the nature of the syringe and the mode of location of the cartridge therewithin, the structure 11 need not clip around or otherwise connect positively to or even engage the end of the cartridge. The cartridge may be held within the body of the syringe in conventional manner e.g. after side loading thereof through the usual side slot or aperture.

CLAIMS

1. A detachable housing for a syringe comprising a drug-containing cartridge (7) having a bung (8) at one end and a penetrable member (9) at the other end, the cartridge being adapted for connection to a needle (17) at the said other end, such that the needle (17) penetrates the penetrable member (9), and being adapted for connection to a plunger mechanism (1) at the said one end, so that the bung (8) can be moved down the cartridge (7) to expel the drug through the needle (17), characterised in that the cartridge (7) is provided with at least one separate structure (11) attachable relative thereto, said structure (11) being adapted for the said connection of the cartridge (7) to the needle (17) and providing means for releasable connection to the plunger mechanism (1), whereby the housing comprising the cartridge (7), the (or each) said structure (11), and the needle (17) can be detached from the plunger mechanism (1) for disposal together.

2. A housing according to claim 1 characterised in that there is one said structure (11) which is attachable to the said other end of the cartridge (7) and which is adapted for connection to the needle (17) and which provides the means for connection to the plunger mechanism (1).

3. A structure for attachment to a drug-containing cartridge of a syringe, which cartridge (7) has a bung (8) at a rearward end and a penetrable membrane (9) at a forward end, said structure (11) being adapted for attachment to a needle (17) and having means (16) for attachment relative to the forward end of the cartridge, and means (15) for attachment to a

plunger mechanism (1).

4. A structure according to claim 3 characterised in that the means (16) for attachment to the forward end of the cartridge comprises means arranged to fit around a neck at the forward end of the cartridge.

5. A structure according to claim 3 or 4 characterised in that said structure (11) is formed integrally with the needle (17).

6. A structure according to claim 3 or 4 characterised in that said structure (11) is formed separately from the needle and incorporates means (13) for connection thereto.

7. A structure according to any one of claims 3 to 6 characterised in that the means (15) for attachment to the plunger mechanism (1) comprises an outer peripheral retaining structure adapted to mate with a corresponding retaining structure at the end of a barrel extension (5) on the plunger mechanism (1).

8. A structure according to any one of claims 3 to 7 characterised by the provision of a sleeve (19) which is mounted on the structure (11) for longitudinal movement forwardly to sheath the needle (17) after use.

9. A structure according to any one of claims 3 to 8 characterised by the provision of a spring arrangement (22 or 24) on the structure (11) which acts to urge the cartridge in a direction away from the needle (17), a releasable retention device (23) being provided to bear on the top rim of the cartridge to resist said urging of the spring arrangement.

10. A housing according to claim 1 or 2 when using the structure of any

one of claims 3 to 9.

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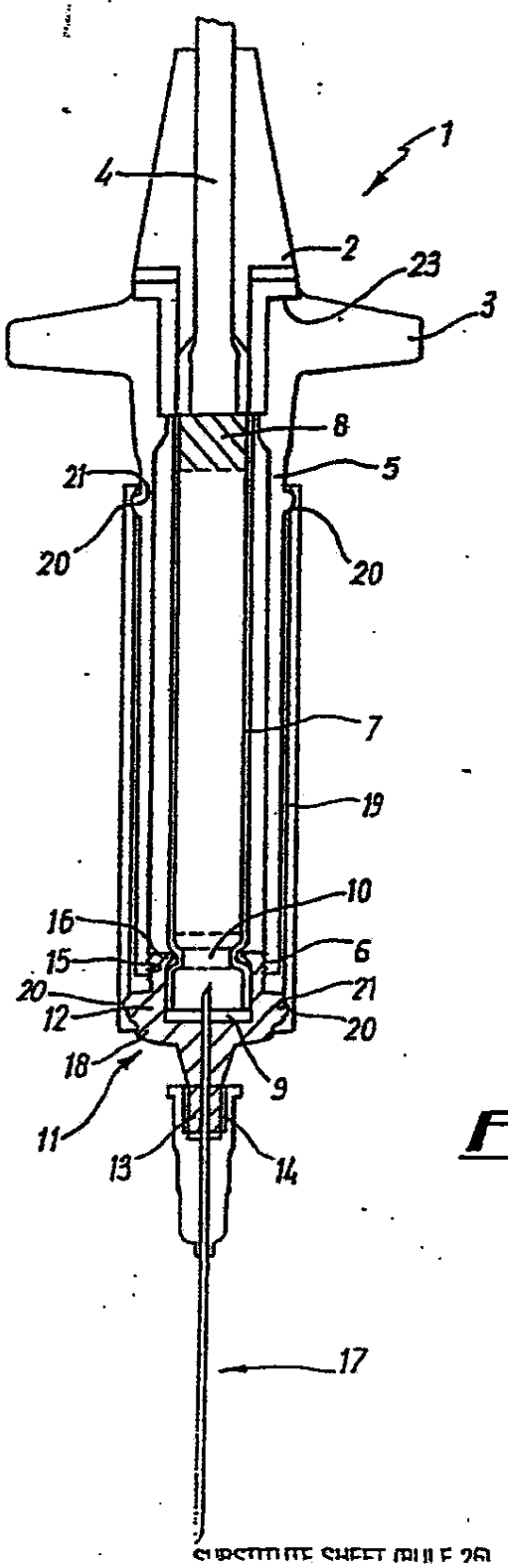

FIG.1

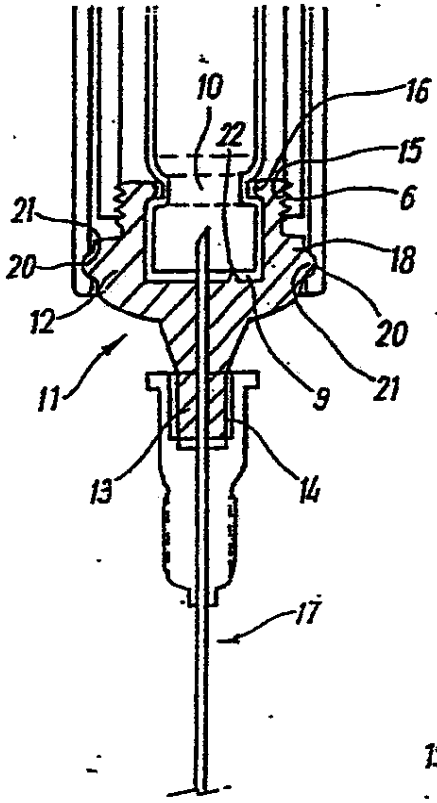
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FIG.2

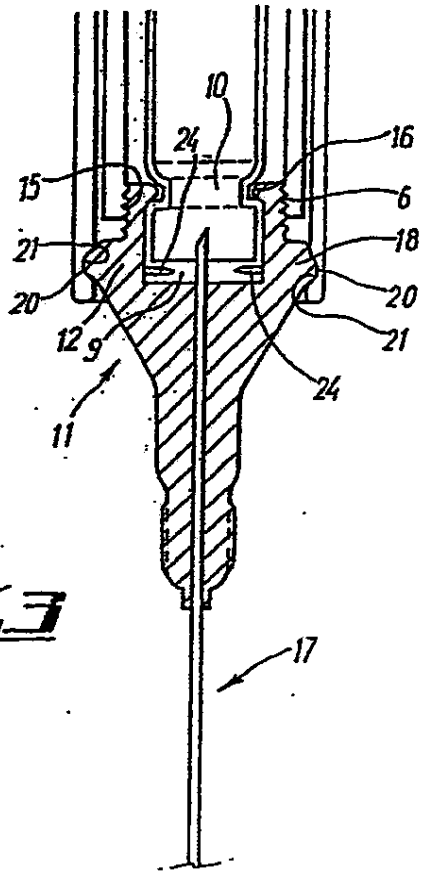
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FIG.3

INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/GB 94/02475

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A,2 778 359 (FRIEDMAN) 22 January 1957 see column 4, line 20 - line 36; figures	1-7,10 8
Y	WO,A,89 04680 (SELDOREN LTD) 1 June 1989 cited in the application see abstract; figures	8
X	US,A,3 825 002 (PAIGE) 23 July 1974 see column 3, line 58 - column 4, line 15; figures	1-7,10
X	US,A,2 671 450 (DANN) 9 March 1954 see the whole document	1-7,10
X	US,A,3 080 866 (FRIEDMAN) 12 March 1963 see column 3, line 57 - column 4, line 9; figures	1-7,10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

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Date of the actual completion of the international search	Date of mailing of the international search report
10 February 1995	09.03.95

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat Application No
PCT/GB 94/02475

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-2778359	22-01-57	NONE		
WO-A-8904680	01-06-89	DE-D-	3887531	10-03-94
		EP-A-	0394295	31-10-90
		GB-A-	2230193	17-10-90
US-A-3825002	23-07-74	NONE		
US-A-2671450	09-03-54	NONE		
US-A-3080866	12-03-63	NONE		

(12) PATENT ABSTRACT
(19) AU (11) AU-A -73 632/81

(54) DISPOSABLE VIAL-SYRINGE

(75) DASKAL, G.

(21) 73 632/81 (22) 3.8.81 (24) 3.8.81
(43) 10.2.83
(51)[3] A61M 5/18

(57) Claim 1. A disposable medicament injector containing its own vial and the vial being 'cylindrical' in shape and having a stopper at each end and the anterior end stopper being able to be pierced by a needle and the (rear) end stopper of the vial being also the anterior part of the plunger and the movements of this anterior part of plunger being inside the vial during use and the medicament - containing vial being enclosed inside the body of a disposable syringe so that these two structures are presented as one structure in a disposable vial / syringe.

Form 10

PATENTS ACT 1952

COMPLETE SPECIFICATION

(ORIGINAL)

FOR OFFICE USE

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Int. Cl:

Application Number:
Lodged:

Complete Specification—Lodged:
Accepted:
Lapsed:
Published:

Priority:

Related Art:

TO BE COMPLETED BY APPLICANT

Name of Applicant: GEORGE DASKAL

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Actual Inventor: GEORGE DASKAL

Address for Service: AS ABOVE

Complete Specification for the invention entitled: DISPOSABLE VIAL/SYRINGE

The following statement is a full description of this invention, including the best method of performing it known to me:—

* Note: The description is to be typed in double spacing, pica type face, in an area not exceeding 250 mm in depth and 170 mm in width,

There exists at present in the field of Dental Analgesia several methods of giving injections. The two most common methods are:

(1) the use of a disposable pre-sterilised cartridge containing the anaesthetic drug and a re-usable metal syringe, and

(2) disposable standard plastic syringe and glass vial containing the anaesthetic drug. The vial is broken and the anaesthetic drug is aspirated into the syringe immediately prior to use in injection procedure.

This patent application presents a syringe which is disposable but which also contains its own drug. It can be said to be a vial / syringe combination. This disposable vial / syringe will also receive a needle which is the operator's choice (in needle length and needle bore size).

The disposable vial / syringe can be pre-sterilised and transported in a sterile state inside a suitable package. Hence, this disposable vial / syringe is ready for use as soon as its protective package is opened. There is no need for further sterilisation prior to use nor for any loading of cartridges or aspirating of anaesthetic drugs. (This eliminates these tedious procedures in a dental surgery and reduces time prior to injections as the disposable vial / syringe is ready for use as soon as its protective package is opened.)

This disposable vial / syringe has a further advantage in the dental surgery in that it has no visible metal parts and it is also smaller than the conventional metal syringe that receives disposable cartridges – both these features make it considerably less threatening to the patient. (Very important in dental surgery use.)

In the broader field of general medical use this disposable vial / syringe has the following advantages:

(1) Emergency use at site of accident because it is ready for immediate use and requires no further sterilisation.

(2) In Third World countries where sterilisation facilities are poor and it requires no further sterilisation prior to use.

(3) With the armed forces in combat situations or during training where equipment carried is kept to a minimum and ability to be used without further sterilisation is an advantage.

The invention is now described in detail with reference to accompanying drawings and numerals relating to parts on the drawings.

The disposable vial / syringe consists of a body of disposable vial / syringe and a plunger. The body is made up of parts labelled 1,2,3,4,5,6,7,11 and the plunger is made up of parts labelled 8,9,10.

Parts 1,2,3,7,8,10,11 are plastics.

Parts 6 and 9 are rubber.

Part 5 is metal.

Part 4 is glass.

The glass cylinder part 4 with the rubber parts 6 and 9 contain the drug to be injected.

Part 6 is immovable, but this rubber part is pierced by the needle (when the needle is attached to part 7) so that the drug can be injected. Part 6 is held on the glass cylinder by metal part 5.

Part 9 is movable by the application of a light force on plunger part 10 and this force must be applied in a line approximately along the long axis of part 4 and the movement of part 9 is also along the long

axis of part 4 (inside the cylinder formed by part 4). For movement of plunger 9 to occur the needle must have first pierced part 6.

Part 1 is the major plastic part of the body of the disposable vial / syringe and houses the drug – containing compartment (4,6,9).

Projections 3 and 2 are on either side of the first and second fingers when the syringe is held in the hand ready for use. Part 2 is in front of the fingers and part 3 is behind the fingers (front and back correspond to operator's front and back when the syringe is held inposition ready for use).

During injection procedure the fingers (first and second) press against part 3 while the thumb presses against part 10 and as the drug is expelled and the plunger moves inside the body of the disposable vial / syringe, the distance between 3 and 10 becomes smaller.

The projections labelled part 2 and the ring shape of 10 allow for aspiration (negative injection).

Aspiration is performed by pressing against 2 with back of first and second fingers and pressing against 10 with back of thumb so that the distance between 2 and 10 is lengthened.

Aspiration is important during block injections to ensure that the needle has not entered a blood vessel prior to injection of the drug. (If needle has entered a blood vessel then blood will be seen in the drug compartment during aspiration procedure.)

The plunger consists of parts 8,9 and 10. Part 10 is a ring into which the thumb of the operator fits.

Part 8 has an end that is conical shaped so that it fits into the cavity in rubber part 9. The

shape of this cavity is such that the conical part of the plunger part 8 can easily enter but can only be removed with difficulty.

Part 7 is for attachment of the needle. This part 7 may be either luer lock or luer grip. The needle used must be "double ended". One end of the needle (shorter end) pierces rubber part 6 and the other end is used to penetrate tissues during the injection procedure.

The claims defining the invention are as follows:

Claim 1. A disposable medicament injector containing its own vial and the vial being 'cylindrical' in shape and having a stopper at each end and the anterior end stopper being able to be pierced by a needle and the (rear) end stopper of the vial being also the anterior part of the plunger and the movements of this anterior part of plunger being inside the vial during use and the medicament - containing vial being enclosed inside the body of a disposable syringe so that these two structures are presented as one structure in a disposable vial / syringe.

Claim 2. The invention of claim 1 with the plunger containing a ring structure (for the thumb) at its distal end and the syringe body having lateral projections with two of these projections immediately at the rear end of body of syringe and another two lateral projections a little distance anteriorly so that operator's fingers that grip the syringe body are bounded by these projections during use.

Claim 3. Invention of claim 1, wherein the vial cylinder containing the medicament is glass and stoppers of vial are rubber (natural or synthetic).

Claim 4. Invention of claim 1 where the syringe part of disposable vial / syringe, as well as the plunger, are made of one of the plastics.

Claim 5. Invention of claim 1 where the anterior projection from body of syringe that is to receive the needle, is of either luer lock or luer grip type.

Claim 6. The invention of claim 1 but where the invention is presented as two parts, one being the body of disposable vial / stringe together with the anterior part of the plunger that forms the rear end stopper of vial compartment, and the other part being the remaining part of plunger, and these two parts are assembled prior to use by pushing plunger part into cavity of distal end stopper.